Supreme Court, U.S.
FILED

08-90 JUL 16 2008

OFFICE OF THE CLERK
William K. Suter, Clerk

No. 08-

IN THE

Supreme Court of the United States

BAYER BIOSCIENCE N.V.,

Petitioner,

v.

MONSANTO COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

VIRGINIA W. HOPTMAN
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
8065 Leesburg Pike
Suite 401
Tysons Corner, VA 22182
(703) 790-3310

GEORGE PAZUNIAK
Counsel of Record
JAMES LENNON
ANNAMARTINA TYREUS
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
222 Delaware Avenue
Suite 1501
Wilmington, DE 19801
(302) 252-4320

Counsel for Petitioner

216973

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

1. Do federal courts have jurisdiction under Article III of the Constitution of the United States to "automatically" adjudicate patents, which present no case or controversy, based solely on a pending claim for attorney fees regarding prior litigation of the patents?

2. Where the sole basis for the federal court's jurisdiction is a claim for attorney fees, must a court enter a final decision for attorney fees before an appellate court may review interlocutory judgments subsidiary to the award of such fees?

3. Once it finds clear error in the district court's finding of material fact, may the Federal Circuit substitute its judgment for that of the district court by making new appellate findings of materiality never addressed by the district court, presuming fraudulent intent from these new findings, and balancing the equities to conclude that there has been inequitable conduct that warrants holding the patent unenforceable?

PARTIES TO THE PROCEEDING

The sole petitioner here and appellant below is Bayer Bioscience, N.V. (formerly known as Aventis CropScience N.V.). The sole respondent here and appellee below is Monsanto Company.

RULE 29.6 STATEMENT

All parent corporations and any publicly held companies that own 10% or more of the stock of Bayer Bioscience, N.V., are Bayer AG; Bayer CropScience AG; and PGS International N.V.

Prior to becoming Bayer BioScience N.V., all parent corporations and any publicly held companies that owned 10% or more of the stock of Aventis CropScience N.V. were Aventis S.A.; Aventis Agriculture S.A.; Hoechst AG; Schering AG; NOR-AM Agro Inc.; Aventis CropScience Holding S.A.; Aventis CropScience GmbH; and PGS International N.V.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
PARTIES TO THE PROCEEDING	ii
RULE 29.6 STATEMENT	ii
TABLE OF CONTENTS	iii
TABLE OF APPENDICES	v
TABLE OF CITED AUTHORITIES	vii
OPINIONS BELOW	1
JURISDICTION	1
CONSTITUTIONAL AND STATUTORY PROVISION INVOLVED	1
STATEMENT OF THE CASE	3
REASONS FOR GRANTING THE PETITION	13
I. THE FEDERAL CIRCUIT'S NEW INTERPRETATION OF ARTICLE III CONFLICTS WITH DECISIONS OF THIS COURT AND OTHER COURTS OF APPEALS	18

Contents

Page

II. THE FEDERAL CIRCUIT EXTENDED ITS APPELLATE AUTHORITY IN CONFLICT WITH THE STATUTORY FINALITY REQUIREMENT AND WITH DECISIONS OF THIS COURT AND OTHER COURTS OF APPEALS 23

III. THE FEDERAL CIRCUIT GROSSLY MISAPPLIED APPELLATE STANDARDS OF REVIEW 27

CONCLUSION 36

TABLE OF APPENDICES

Page

Appendix A — Opinion Of The United States Court Of Appeals For The Federal Circuit Decided April 23, 2008 ..... 1a

Appendix B — Opinion Of The United States Court Of Appeals For The Federal Circuit Decided January 25, 2008 As Amended By Errata January 25, 2008 ..... 5a

Appendix C — Judgment Of The United States District Court For The Eastern District Of Missouri, Eastern Division Dated April 12, 2007 ..... 37a

Appendix D — Memorandum And Order Of The United States District Court For The Eastern District Of Missouri, Eastern Division Dated April 12, 2007 ..... 38a

Appendix E — Final Judgment Of The United States District Court For The Eastern District Of Missouri, Eastern Division Dated September 25, 2006 ..... 63a

Appendix F — Memorandum And Order Of The United States District Court For The Eastern District Of Missouri, Eastern Division August 28, 2006 ..... 65a

Appendices

Page

Appendix G — Memorandum And Order Of The United States District Court For The Eastern District Of Missouri, Eastern Division Dated January 10, 2005 ..... 209a

Appendix H — Order Of The United States Court Of Appeals For The Federal Circuit Denying Petition For Rehearing And Petition For Rehearing En Banc Filed April 17, 2008 ..... 228a

Appendix I — Errata Of The United States Court Of Appeals For The Federal Circuit Decided January 25, 2008 ..... 230a

TABLE OF CITED AUTHORITIES

Page

Cases

Bender v. Williamsport Area School District, 475 U.S. 534 (1985) 18

Benitec Australia, LTD v. Nucleonics, Inc., 495 F.3d 1340 (Fed. Cir. 2007) 19

Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226 (Fed. Cir. 2003) 30

Brooks Furniture Mfg. v. Dutailier Int'l, Inc., 393 F.3d 1378 (Fed. Cir. 2005) 24

Cardinal Chem. Co. v. Morton Int'l Inc., 508 U.S. 83 (1993) 15, 16

Catlin v. United States, 324 U.S. 229 (1945) 26

Church & Dwight Co., Inc. v. Abbot Labs, 2008 WL 2565548 (D.N.J. 2008) 14

Citizens for Resp. Gov't State Pol. Action Comm. v. Davidson, 236 F.3d 1174 (10th Cir. 2000) 21

Cobbledick v. United States, 309 U.S. 323 (1940) 26

Cited Authorities

Page

Cohen v. Beneficial Industrial Loan Corp.,
337 U.S. 541 (1949) 26

Corpus Christi Taxpayer's Ass'n. v. City of Corpus Christi,
858 F.2d 973 (5th Cir. 1988) 34

DeMarco v. United States,
415 U.S. 449 (1974) 28

Diamond v. Charles,
476 U.S. 54 (1986) 3, 20

Duffie v. Deere & Co.,
111 F.3d 70 (8th Cir. 1997) 34

Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank,
527 U.S. 627 (1999) 24

Fort Knox Music Inc. v. Baptiste,
203 F.3d 193 (2d Cir. 2000) 34

Gardco Manufacturing, Inc. v. Herst Lighting Co.,
820 F.2d 1209 (Fed. Cir. 1987) 25

General Elec. v. Joiner,
522 U.S. 136 (1997) 29

Cited Authorities

Page

General Motors Corp. v. Devex Corp.,
461 U.S. 648 (1983) 24

Giovanni Carandola, Ltd. v. City of Greensboro,
2007 WL 4322196 (4th Cir. 2007) 21

Hensley v. Eckerhart,
461 U.S. 424 (1983) 16

Honeywell Intern. Inc. v. Universal Avionics Systems Corp.,
488 F.3d 982 (Fed. Cir. 2007) 30

Johansen v. United States,
506 F.3d 65 (1st Cir. 2007) 21

Jones v. Jones Bros. Constr. Corp.,
879 F.2d 295 (7th Cir. 1989) 34

Keefe v. Bahama Cruise Line, Inc.,
867 F.2d 1318 (11th Cir. 1989) 34

Kelley v. Everglades Drainage District,
319 U.S. 415 (1943) 28

Kokkonen v. Guardian Life Ins. Co. Of America,
511 U.S. 375 (1994) 18

Lewis v. Continental Bank Corp.,
494 U.S. 472 (1990) 3, 20

Cited Authorities

Page

Liu v. I.N.S.,
274 F.3d 533 (D.C. Cir. 2001) 20

Marbury v. Madison,
5 U.S. 137 (1803) 18

Maryland Casualty Co. v. Pacific Coal & Oil Co.,
312 U.S. 270 (1941) 18, 22

Medimmune, Inc. v. Genentech, Inc.,
535 F.Supp.2d 1000 (C.D. Cal. 2008) 14

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118, 127 S.Ct. 764 (2007) 18, 22

Molins PLC v. Textron, Inc.,
48 F.3d 1172 (Fed. Cir. 1995) 30

Monsanto Co. v. Bayer BioScience N.V.,
363 F.3d 1235 (Fed. Cir. 2004) 5

New York State Fed. of Taxi Drivers v. Westchester Cty Taxi and Limousine Comm'n,
272 F.2d 154 (2nd Cir. 2001) 21

Nilssen v. Osram Sylvania, Inc.,
504 F.3d 1223 (Fed. Cir. 2007) 10, 11, 14, 15

Cited Authorities

Page

North Carolina v. Rice,
404 U.S. 244 (1971) 19

OCI Wyo., L.P. v. PacifiCorp,
479 F.3d 1199 (10th Cir. 2007) 34

O'Neal v. Gresham,
519 F.2d 803 (4th Cir. 1975) 34

Preiser v. Newkirk,
422 U.S. 395 (1975) 18-19

Purcell v. Gonzalez,
549 U.S. 1 (2006) 29

S-1 v. Spangler,
832 F.2d 294 (4th Cir. 1987) 21

Security Farms v. International Bhd. of Teamsters,
124 F.3d 999 (9th Cir. 1997) 34

Serio-US Industries, Inc. v. Plastic Recovery Technologies Corp.,
459 F.3d 1311 (Fed. Cir. 2006) 24-25

Sprint/United Management Co. v. Mendelsohn,
128 S. Ct. 1140 (2008) 5, 29, 30

Page

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054 (Fed. Cir. 1995) 19

Texaco Ref. & Mktng Inc. v. Davis, 45 F.3d 437, 1994 WL 721801 (9th Cir. 1994) ... 21

United States v. Ford, 954 F.2d 1441 (9th Cir. 1992), *cert denied*, 455 U.S. 942 (1982) 21

United States. v. Merz, 376 U.S. 192 (1964) 29

Willy v. Coastal Corp., 503 U.S. 131 (1992) 21

Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100 (1969) 21

Statutes

15 U.S.C. § 2805(d) 21

26 U.S.C. § 7430 21

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1291 ..... 17, 26, 27

Cited Authorities

Page

28 U.S.C. § 1295 ..... *passim*

28 U.S.C. § 2201 ..... 2, 5

35 U.S.C. § 285 ..... *passim*

42 U.S.C. § 1988 ..... 16, 20

Rules

37 C.F.R. § 1.56 ..... *passim*

FED. R. CIV. P. 11 ..... 21, 24

FED. R. CIV. P. 52 ..... 28, 35

FED. R. EVID. 403 ..... 29, 30

Treatises

Wright & Miller,
Fed. Prac. & Proc. Civ.2d § 2571 (2008) 29

Constitutional Provisions

U.S. CONST. art. III, § 2 ..... 1, 18

OPINIONS BELOW

The opinion of the U.S. Court of Appeals for Federal Circuit in Case No. 2007-1109 (App. 5a-36a) is reported at 514 F.3d 1229. The opinion of the Federal Circuit in Case No. 2007-1299 (App. 1a-4a) is unreported, but can be found at 2008 WL 1808369. Two decisions of the district court are relevant. The first (App. 65a-208a) is unreported. The second (App. 40a-64a) is also unreported and can be found at 2007 WL 1098504.

JURISDICTION

The Federal Circuit denied a petition for rehearing or rehearing *en banc* in Case No. 2007-1109 on April 17, 2008, and entered judgment in Case No. 2007-1299 on April 23, 2008. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISION INVOLVED

Article III, Section 2 of the Constitution of the United States provides in relevant part:

> The judicial power shall extend to all cases, in law and equity, arising under this Constitution, the laws of the United States . . . ; —to controversies . . . between citizens of different states;—between citizens of the same state claiming lands under grants of different states, and between a state, or the citizens thereof, and foreign states, citizens or subjects.

U.S. CONST. art. III, § 2.

The Patent Code, 35 U.S.C. § 285, provides:

> The court in exceptional cases may award reasonable attorney fees to the prevailing party.

The Declaratory Judgment Act, 28 U.S.C. § 2201(a), provides in relevant part:

> (a) In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

The appellate authority of the Federal Circuit is based on 28 U.S.C. § 1295 (a)(1), which provides in relevant part:

> (a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—
>
> (1) of an appeal from a final decision of a district court of the United States . . . , if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title . . . .

STATEMENT OF THE CASE

This case presents the question of whether a federal court may enter a declaratory judgment adjudicating otherwise admittedly non-justiciable issues, based on an interlocutory finding regarding a claim for attorney fees. In two remarkable decisions below, the Federal Circuit held that the attorney fee statute, 35 U.S.C. § 285, grants retroactive jurisdiction and requires district courts to "automatically" declare dismissed patents unenforceable if the district court determines that the patents had been inequitably procured while adjudging the claim for attorney fees. The Federal Circuit thus created an unprecedented exception to the case or controversy requirement of Article III and the Declaratory Judgment Act by holding that, at least in some circumstances, federal courts are not bound by the Constitutional and statutory requirements, and are to enter judgments as to matters that otherwise present no case or controversy.

These decisions are important at the most basic level of federal jurisprudence. They represent an extremely dangerous interpretation of Article III and the Declaratory Judgment Act by marginalizing the basic case or controversy requirement, and expanding federal court jurisdiction in direct conflict with many of this Court's decisions, including *Lewis v. Continental Bank Corp.*, 494 U.S. 472 (1990) and *Diamond v. Charles*, 476 U.S. 54 (1986). In these cases, this Court held that a claim for attorney fees is insufficient to create Article III jurisdiction regarding issues that have been rendered moot. No legal principle supports the Federal Circuit's fashioning of a so-called "automatic

judgment" exception to allow interlocutory findings in a discrete adjudication (in this case a petition for attorney fees) to determine jurisdiction *vel non* over declaratory judgment claims that had been previously dismissed as moot. Having been created by fiat and not founded on any law or legal principles, this expansion of Article III jurisdiction applies nationwide to all cases that must be appealed to the Federal Circuit, and it sets a dangerous precedent for other Circuits in non-patent cases.

Equally troubling is the Federal Circuit's unprecedented expansion of its appellate authority by holding that the resulting "automatic" judgment had to be appealed immediately, even though it was interlocutory to the attorney fees claim, which the district court had not yet adjudicated and which was the sole basis for the district court's Article III jurisdiction. On this basis, the Federal Circuit expanded its appellate authority to review the merits of the district court decision before final judgment, contrary to the statutory limitations on appellate jurisdiction set forth in 28 U.S.C. § 1295, as well as the teachings of this Court and other Circuits. As a result, the decisions below denied substantive review of the interlocutory findings of inequitable conduct, specifically holding that substantive review was available only from the initial judgment of "unenforceability," even though that judgment had no independent jurisdictional basis.

Finally, with respect to the single patent still in suit, the Federal Circuit further expanded its authority— this time at the expense of the district court — by making new appellate findings of materiality never addressed

by the district court, presuming an inference of fraudulent intent from these new findings, and substituting its judgment for the district court's exercise of discretion. This is inconsistent with the long-established teachings of this Court, confirmed most recently in *Sprint/United Management Co. v. Mendelsohn*, 128 S. Ct. 1140 (2008).

Statement of Relevant Facts and Proceedings Below

The District Court Proceedings

Respondent Monsanto Company ("Monsanto") originally filed an action under the Declaratory Judgment Act, 28 U.S.C. § 2201(a), against the predecessor to Petitioner Bayer BioScience N.V. (Petitioner and all predecessor entities are collectively referred to as "Bayer"). Monsanto sought a declaratory judgment that four of Bayer's patents, Pat. Nos. 5,545,565 ("the '565 patent"), 5,767,372 ("the '372 patent"), 6,107,546 ("the '546 patent") and 5,254,799 ("the '799 patent"), were invalid, unenforceable, and not infringed. Bayer counterclaimed, alleging infringement of certain claims of each patent. Monsanto later claimed attorney fees under 35 U.S.C. § 285, arguing that Bayer had asserted patents which were inequitably procured. After a period of litigation, and shortly after obtaining a favorable judgment from the Federal Circuit, *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235 (Fed. Cir. 2004), Bayer dismissed all claims under three of the four patents by filing an unconditional statement of non-liability, covenanting not to sue Monsanto for any past, present or future infringement of the '799, '372 and '546 patents (collectively the "dismissed patents").

(D.I. 448)[1] The district court instructed at that time that Bayer's covenant "remov[ed] any case or controversy with respect to all patents except the '565 patent." (App. 212a) There was no dispute between the parties, and no challenge by the Federal Circuit, that such covenants eliminated any Article III jurisdiction with respect to the dismissed patents, except to decide Monsanto's claims for attorney fees regarding prior litigation of the patents.

The validity and infringement of the '565 patent was tried to a jury from November 1 to November 22, 2005. The jury returned a verdict for Monsanto. (D.I. 797) In the subsequent appeal, the Federal Circuit did not review Bayer's claims of error related to the jury verdict as a result of its decisions on unenforceability.

The covenant and the jury verdict did not end the case, however, because Monsanto had demanded attorney fees under 35 U.S.C. § 285, alleging that the case was "exceptional" because all four patents, which Bayer had at some time enforced against Monsanto, had been procured through inequitable conduct. Therefore, the district court held a bench trial, on February 21-24, 2006, to determine whether the three dismissed patents were inequitably procured, and whether the '565 patent, which was still in issue, was also inequitably procured. With respect to the three dismissed patents, the only issue was whether Monsanto was entitled to attorney fees under § 285 for the period that Bayer had asserted them against Monsanto.

---

[1] All citations to record evidence are to docket items ("D.I.") in case 4:00cv1915 in the Eastern District of Missouri.

Monsanto presented different theories to support its claims of inequitable conduct: one set of allegations with respect to the '565 patent, and a completely different set of allegations with respect to the dismissed '799 patent. The two other dismissed patents were never mentioned during trial, and Monsanto presented no evidence as to them. On August 28, 2006, the district court found that the '565 and '799 patents were inequitably procured. But contrary to the district court's earlier clear recognition that it had no jurisdiction over the dismissed patents except for purposes of determining attorney fees under § 285, and with no evidence or findings regarding two of the dismissed patents, the district court summarily ordered and entered a final judgment that all *four* Bayer patents were unenforceable on September 25, 2006. (App. 208a; 64a)

With respect to the single patent still in suit, the district court determined that the '565 patent was unenforceable because Bayer's European patent agent had failed to disclose to the U.S. Patent and Trademark Office a page of handwritten notes during the patent's prosecution.[2] The notes were included on an abstract of a poster presentation by a third party, Dr. Barnes. The agent had provided the Barnes abstract to the Patent Office, but had not provided the handwritten notes. The district court concluded that the notes were "highly material" under 37 C.F.R. § 1.56(b)(1), at least in part, because it erroneously believed that the "notes

[2] This is the only finding of inequitable conduct reviewed on appeal. Indeed, the Federal Circuit never reviewed any findings regarding the dismissed patents because it found that Bayer had waived its right to appellate review.

coded for the same 67 Kd toxic protein Bayer wanted to claim," and, therefore, "[t]he . . . notes by themselves, withheld by Bayer from the PTO examiner, if disclosed, would establish a *prima facie* case of unpatentability of Bayer's claims under the '565 patent." (App. 206a) The district court articulated no other specific basis for its conclusion that the notes were highly material and made no other specific materiality findings from which to infer fraudulent intent.

After the district court's ruling, Monsanto filed a motion under 35 U.S.C. § 285 for a determination that the case was "exceptional" and assessment of attorney fees. (D.I. 898) The matter was briefed, and on April 12, 2007, the trial court entered its final order and Judgment under 35 U.S.C. § 285, finding that the case was exceptional and awarding attorney fees. (App. 37a)

Bayer's Appeal

On October 24, 2006, Bayer timely appealed the district court's September 25, 2006 judgment. Bayer requested, in relevant part, that the Federal Circuit vacate the declaration of unenforceability of the three dismissed patents because the district court lacked Article III subject matter jurisdiction. Bayer specifically argued that the Federal Circuit should review the inequitable conduct finding as to the dismissed patents only upon appeal of the final award of attorney fees, if any, because the inequitable conduct judgment as to the three dismissed patents was interlocutory to the § 285 determination, which was the sole basis for the federal court's jurisdiction.

With regard to the '565 patent, Bayer argued *inter alia* that the finding of inequitable conduct should be reversed, because the district court's "highly material" finding was clearly erroneous. There was no evidence, and no one — not even Monsanto — ever suggested that "the Barnes notes coded for the same 67 Kd toxic protein Bayer wanted to claim," which was the only fact that the district court specifically articulated to support materiality. (App. 206a) Indeed, the evidence was undisputed that no one could tell then, and it is still unknown today, what gene or protein Barnes had used.

On April 23, 2007, Bayer filed its second appeal, this time from the April 12, 2007 order and judgment, which found exceptional case and awarded attorney fees under 35 U.S.C. § 285. (D.I. 924) Bayer, *inter alia*, asserted serious errors by the trial judge in its interlocutory findings of inequitable conduct as to the dismissed '799 patent, and in finding that the two other dismissed patents were "unenforceable" without any evidence or findings of inequitable conduct. Bayer requested that any award of attorney fees be properly apportioned in light of the absence of any evidence of inequitable prosecution as to two of the patents, and the failure of proof as to the other two patents.

The Appellate Decisions

In the first appeal, Case No. 2007-1109, the Federal Circuit held that, even though there was admittedly no Article III case or controversy between the parties regarding the three dismissed patents, 35 U.S.C. § 285 authorized the district court to enter the final judgment that the dismissed patents were "unenforceable."

The Federal Circuit held that Bayer's jurisdictional objection based on Article III was merely one of "semantics," reasoning that once a court determined, as part of its § 285 inquiry, that Bayer had enforced a patent infected with inequitable conduct, the district court had no choice but to "automatically" declare the patent unenforceable, regardless of jurisdiction:

> A district court has no discretion to decide whether a patent is unenforceable once it enters a finding of inequitable conduct. To the contrary, this court has long held that the unenforceability of a patent follows automatically once a patent is found to have been obtained via inequitable conduct. . . . As a result, jurisdiction to decide whether a patent was obtained through inequitable conduct necessarily includes the jurisdiction to declare a patent unenforceable as a result of that inequitable conduct.

(App. 34a-35a)

To support its unprecedented conclusion that "jurisdiction [under § 285] to decide whether a patent was obtained through inequitable conduct [in the course of determining whether a case had been exceptional] necessarily includes the [Article III] jurisdiction to declare a patent unenforceable as a result of that inequitable conduct," the Federal Circuit relied on its earlier decision in *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed. Cir. 2007), which the Federal Circuit characterized as having "explicitly held that a district

court has the power to declare patents that are no longer in suit unenforceable for inequitable conduct." (App. 35a)[3]

Thus, the Federal Circuit postulated not only the right, but the obligation, of federal courts to adjudicate patents without regard to Article III jurisdiction, so long as the patents were related to other litigation — such as the discrete claims for attorney fees in the instant case or relationship to other patents in litigation in *Nilssen*.

The Federal Circuit then extended its newly-created jurisdictional exception to Article III a step further. It held that even though § 285 was the only jurisdictional basis for the inequitable conduct finding, the resulting interlocutory "unenforceability" judgment — not the final § 285 judgment — was the final decision for purposes of appeal. That is, the unenforceability judgment now not only adjudicated moot issues, but stood independently of the original § 285 proceeding that was the original and only basis for the court's jurisdiction. As a result, the Federal Circuit held that Bayer had waived any substantive challenge to the interlocutory findings of inequitable conduct regarding the dismissed patents by filing these challenges only in

---

[3] Contrary to the Federal Circuit's interpretation of *Nilssen*, the district court in that case did not enter a judgment holding any of the withdrawn patents unenforceable, but entered findings of inequitable conduct regarding withdrawn patents only in the context of determining infectious and other unenforceability issues regarding the patents still in suit. *Nilssen v. Osram Sylvania, Inc.*, 440 F. Supp. 2d 884, 893-94, 896 fn.5 & 910-11 (N.D. Ill. 2006).

the appeal of the final § 285 judgment awarding attorney fees. (App. 2a-4a and 36a fn. 18)

Regarding the single '565 patent still in issue, the district court's only specific finding of materiality was that the notes disclosed the same gene sequence claimed in the '565 patent, thereby establishing a *prima facie* case of unpatentability under 37 C.F.R. §1.56 (b)(1). (App. 206a) The Federal Circuit rejected this critical finding of material fact by the district court, admitting that "Bayer is correct that there is nothing in the record which would support a finding that the Bt toxin used by Barnes was identical to the Bt toxin claimed in the issued '565 patent," and referencing the district court's "untenable reading of the notes as stating that the Barnes Poster disclosed a gene coding for the same Bt toxin used by Bayer." (App. 22a-23a, 27a) But rather than vacating and remanding the case to the district court, the Federal Circuit *sua sponte* re-analyzed the facts to find new, alternative reasons why the handwritten notes might nonetheless be material under a different materiality standard. The Federal Circuit did so by finding an entirely new and different basis for the materiality of the handwritten notes, which had never been argued by the parties or addressed by either the district court or the parties on appeal. Indeed, the new argument for materiality invoked an entirely different rule in the Patent Office, 37 C.F.R. §1.56(b)(2)(i), which also had never been addressed by the trial court or the parties on appeal with respect to the handwritten notes. Based on the new fact findings, the Federal Circuit determined that in the exercise of its *appellate* discretion, it would find the patent unenforceable for inequitable conduct, and, on this inappropriate basis, affirmed the district court. (App. 26a-27a)

In Case No. 2007-1299, Bayer had appealed the district court's substantive finding of inequitable conduct with respect to the three dismissed patents, arguing clear error in the district court's analysis of the dismissed '799 patent and in its summary treatment of the other two dismissed patents without any evidence in the record regarding these patents. However, based on its prior decision in Case No. 2007-1109 upholding jurisdiction to declare the three dismissed patents unenforceable for inequitable conduct, the Federal Circuit relied on the law of the case to refuse to consider Bayer's challenge to the merits of the district court findings of inequitable conduct in this appeal. (App. 2a-4a) As a result, the Federal Circuit affirmed the district court's judgment awarding attorney fees on the ground that Bayer's appeal was moot.

REASONS FOR GRANTING THE PETITION

The Federal Circuit expanded federal judicial power without addressing Article III, the Declaratory Judgment Act or precedent (other than its own), but simply found federal jurisdiction by fiat. Given the radical expansion of federal judiciary into matters which admittedly present no case or controversy and novel proposition of exceptions to Article III, the Federal Circuit's decision should be considered by the Court. The conflicts with this Court's prior precedent and those of other Circuits, and the adverse effect on procedures and practices of patent litigation, are many and significant.

Besides unduly excepting Article III, the decisions are contrary to the clear holdings of this Court, as well

as those of other Circuits, as detailed below, that an interest in attorney fees does not create an Article III case or controversy where none otherwise exists on the underlying merits. The Court should address that conflict, and particularly whether the Federal Circuit is correct that Article III's limitations of federal judicial authority — which underlie those decisions of this Court and the other Circuits – can be replaced by the principle of "automatic" judgments.

But, the Federal Circuit did not limit its expansion of judicial power solely to instances where there are pending claims for attorney fees, as Constitutionally problematic that exercise is by itself. Its rulings, coupled with its citation to its prior *Nilssen* case, authorizes — indeed, compels — the federal courts to enter judgments "automatically" in matters that do not involve any case or controversy whenever there is a patent-related interlocutory finding in a patent proceeding. *Nilssen*, after all, did not involve § 285 or any claim for attorney fees. Thus, the Federal Circuit's ruling requires all district courts to render advisory opinions regarding patents which present no case or controversy.

This expanded and erroneous view of federal jurisdiction has already begun to take hold in the federal courts in just the few short months since the decisions below. In *Medimmune, Inc. v. Genentech, Inc.*, 535 F.Supp.2d 1000, 1005 n.1 (C.D. Cal. 2008), the district court, citing the case on appeal, held that "courts will often have the ability to hear an unenforceability claim on a patent regardless of jurisdiction." *See also Church & Dwight Co., Inc. v. Abbot Labs*, 2008 WL 2565548 (D.N.J. 2008) ("Once inequitable conduct has been

proved, 'the unenforceability of a patent follows automatically'") (citing case on appeal).

Further, although both the present case and *Nilssen* involved judgments of "unenforceability" upon a finding of inequitable conduct, the ruling here and the Federal Circuit's reference to *Nilssen* applies equally to any interlocutory finding that may be made, such as interlocutory findings of the invalidity, infringement, licensing or any other issue that may be raised under § 285 or in another proceeding. And, the Federal Circuit's jurisdictional rulings are not confined to the patent context, but reach deeply into Article III itself, ensnaring every matter within the scope of its exclusive appellate authority under 28 U.S.C. § 1295. Thus, the Federal Circuit's holding opens the door for district courts across the country to render advisory opinions, involving at least patents or other matters which are within the Federal Circuit's appellate authority, regardless of jurisdiction, where there is no controversy between the parties regarding the enforcement of the underlying patent or other rights, as long as a claim for attorney fees is made or some other indirect relationship of subject matter.

Review of these errors is urgently needed. Because the Federal Circuit is the sole appellate court for patent claims from all United States District Courts, its unprecedented expansion of Article III jurisdiction based on a residual attorney fees claims "is a matter of special importance to the entire Nation." *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89 (1993).

Further, although the issue here involved 35 U.S.C. § 285, which is part of the patent statutes, the rationale will apply to all federal laws involving attorney fees that may be raised within the Federal Circuit's appellate authority and across all other Circuits. This follows, because § 285 is similar to the many other fee-shifting statutes that "Congress . . . has authorized . . . , such as the Civil Rights Act of 1964, 78 Stat. 259, 42 U.S.C. § 2000e-5(k), the Voting Rights Act Amendments of 1975, 89 Stat. 402, 42 U.S.C. § 1973l(e), and the Civil Rights Attorney's Fees Awards Act of 1976, 90 Stat. 2641, 42 U.S.C. § 1988." *Buckhannon Bd. & Care Home, Inc. v. West Virginia Dep't. Of Health & Human Res*, 532 U.S. 598, 602-03 (2001). The Court further noted that:

> We have interpreted these fee-shifting provisions consistently, see *Hensley v. Eckerhart*, 461 U.S. 424, 433, n. 7, 76 L. Ed. 2d 40, 103 S. Ct. 1933 (1983), and so approach the nearly identical provisions at issue here.

Buckhannon, 532 U.S. at 603 fn. 4. Therefore, for the Circuit Courts to follow this Court's admonition for consistency, the Federal Circuit's rule here will become the law across the country.

Equally important, in view of *Cardinal Chem., supra*, is that the Federal Circuit's rationale that federal courts may, and perhaps must, automatically enter judgments with respect to patents which have been removed from contention undermines efficiency and certainty in the judicial system. Indeed, covenants of non-liability are often used in the courts precisely to promote these goals by freeing a target party from any

liability potential and eliminating the potential risk of a negative adjudication to the patent owner, while eliminating the cost and uncertainty of litigation for both. The bedrock assumption underlying their use and the balanced benefits of the covenants has now been significantly undermined, and may reduce their use.

Equally problematic is the Federal Circuit's expansion of its appellate authority to include review of interlocutory findings in contravention of the final-decision limitation set forth in 28 U.S.C. § 1295. In a clear departure from decisions of this Court and other Circuits under the parallel provision in § 1291, the Federal Circuit determined that parties must appeal interlocutory judgments, made in the course of adjudging claims under 35 U.S.C. § 285, before the district court has made its § 285 finding. This cavalier treatment of the finality requirement for appellate jurisdiction, if allowed to stand, will force litigants across the country to appeal interlocutory judgments piecemeal to avoid the risk of losing the right to obtain appellate review.

Finally, the Federal Circuit's decision to independently analyze materiality, fraudulent intent and balance the equities once it found clear error in the district court's finding of materiality also warrants review, because it departs so drastically from the standard of appellate review established by this Court followed by other Circuits. This issue does not, however, affect the Federal Circuit's Article III and statutory jurisdiction analysis, which independently warrant the grant of certiorari on Questions 1 and 2.

I. The Federal Circuit's New Interpretation of Article III Conflicts with Decisions of This Court and Other Courts of Appeals

Marbury v. Madison, 1 Cranch 137, 173-180, 5 U.S. 137 (1803) established that federal courts have only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto, a rule that has been inflexibly followed through jurisprudential generations. "Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute, which is not to be expanded by judicial decree." *Kokkonen v. Guardian Life Ins. Co. Of America*, 511 U.S. 375, 377 (1994) (internal citations omitted); *see also Bender v. Williamsport Area School District*, 475 U.S. 534 (1985).

Article III of the Constitution requires that federal courts adjudicate only actual, ongoing cases or controversies. U.S. Const. art. III, § 2; *see, e.g., Deakins v. Monahan*, 484 U.S. 193, 199 (1988). To satisfy the case-or-controversy requirement, there must be "'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S.Ct. 764, 771 (2007) (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). A federal court lacks the power to render advisory opinions or to "decide questions that cannot affect the rights of litigants in the case before them. Its judgments must resolve 'a real and substantial controversy admitting of specific relief through a decree of a conclusive character.'" *Preiser v. Newkirk*, 422 U.S.

395, 401 (1975) (quoting *North Carolina v. Rice*, 404 U.S. 244, 246 (1971)). This case-or-controversy requirement of Article III and the Declaratory Judgment Act must subsist through all stages of the federal litigation proceedings. *See, e.g,. Deakins*, 484 U.S. at 199.

In this case, it is undisputed that there was no case or controversy regarding the dismissed patents. After an earlier successful appeal, Bayer filed an unconditional statement of non-liability, covenanting not to sue Monsanto for any past, present or future infringement of these patents. The district court was correct when it initially held — without any dispute by Monsanto or by the Federal Circuit — that Bayer's statement of non-liability "remov[ed] any case or controversy with respect to all patents except the '565 patent." (App. 212a) Such covenants have long been held to remove any jurisdiction as to the patents subject to the covenants. *See, e.g., Deakins*, 484 U.S. at 199 (dismissal with prejudice moots claims); *Benitec Australia, LTD v. Nucleonics, Inc.*, 495 F.3d 1340, 1347-48 (Fed. Cir. 2007); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059-60 (Fed. Cir. 1995). Nothing changed the jurisdictional posture of the case between the district court's initial holding and its subsequent *sua sponte* entry of a purported adjudication of "unenforceability." Thus, the district court's own recognition that there was no "case or controversy" regarding the dismissed patents should have precluded any judgment as to those patents (obviously without affecting whatever rights Monsanto had to pursue its claims for attorney fees under § 285).

The Federal Circuit's decision — that a district court's jurisdiction to award attorney fees under 35 U.S.C. § 285 confers on that court jurisdiction to hold unenforceable patents that are otherwise no longer in suit – directly defies the teachings of this Court and other Circuits under similar fee-shifting statutes. In *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990), this Court held that a claim for attorney fees under 42 U.S.C. § 1988 could not create Article III jurisdiction regarding issues that had been rendered moot. After holding that an "interest in receiving attorney's fees is, of course, insufficient to create an Article III case or controversy where none exists on the merits of the underlying claim," this Court cautioned that when "the only concrete interest in the controversy has terminated, reasonable caution is needed to be sure that mooted litigation is not pressed forward, and unnecessary pronouncements on even constitutional issues obtained, solely in order to obtain reimbursement of sunk costs." *Lewis*, 494 U.S. at 480; *see also Diamond v. Charles*, 476 U.S. 54, 70-71 (1986).

Moreover, to the extent that the Federal Circuit supported its new rule as an extension of the patent fee-shifting, its decision is completely at odds with how the Declaratory Judgment Act and Article III are construed in other Circuits. For example, the D.C., First, Second, Fourth, Ninth, and Tenth Circuits have each recognized that fee-shifting statutes, which confer jurisdiction on the federal courts to resolve claims for attorney fees, are insufficient to confer Article III jurisdiction regarding the merits of other claims where no case or controversy otherwise exists. *Liu v. I.N.S.*, 274 F.3d 533, 536 (D.C. Cir. 2001) (interest in attorney

fees insufficient to create Article III jurisdiction); *Johansen v. United States*, 506 F.3d 65 (1st Cir. 2007) (claim for attorney fees under 26 U.S.C. § 7430 and 28 U.S.C. § 2412(d) insufficient to maintain Article III jurisdiction); *New York State Fed. of Taxi Drivers v. Westchester Cty Taxi and Limousine Comm'n*, 272 F.2d 154 (2nd Cir. 2001) (interest in attorney fees insufficient to create Article III jurisdiction); *S-1 v. Spangler*, 832 F.2d 294, 297n.1 (4th Cir. 1987) ("a claim for costs and attorney's fees . . . does not avert mootness of the underlying action on the merits"), *quoted in Giovanni Carandola, Ltd. v. City of Greensboro*, 2007 WL 4322196 *2 (4th Cir. 2007); *United States v. Ford*, 954 F.2d 1441, 1450 (9th Cir. 1992), *cert denied*, 455 U.S. 942 (1982), *cited in Texaco Ref. & Mktng Inc. v. Davis*, 45 F.3d 437, 1994 WL 721801 (9th Cir. 1994) (unpublished opinion) (claim for attorney fees under 15 U.S.C. § 2805(d) as prevailing party in TRO request does not revive otherwise moot issue); *Citizens for Resp. Gov't State Pol. Action Comm. v. Davidson*, 236 F.3d 1174 (10th Cir. 2000) (pending claim for attorney fees does not revive an otherwise moot issue).

Like other fee-shifting statutes, the determination of "exceptional case" and award of attorney fees under § 285 is entirely independent of the federal court's jurisdiction over the underlying action. *Cf.*, *Willy v. Coastal Corp.*, 503 U.S. 131 (1992) (holding that district court could sanction party under FED. R. CIV. P. 11, even if the court did not have jurisdiction of the subject matter of the case). And, like other fee-shifting statutes, § 285 jurisdiction extends only to whether attorney fees already incurred may be recovered, not to decide underlying claims that have been rendered moot. The

Federal Circuit viewed this jurisdictional difference as merely one of "semantics," reasoning that once a court makes a finding of inequitable conduct, the patent law requires that the patent be held unenforceable. But this analysis misses the fundamental limitation imposed on federal courts by the case-or-controversy requirement of Article III: federal courts simply do not have the power to render opinions regarding the legal consequences of interlocutory findings when there remains no case or controversy between the parties.

The expediency of making the judgment "automatic" based on other litigation does not and can not replace Article III's case or controversy requirement. Article III is not a procedural rule, and it does not serve convenience or expediency, but is a Constitutional limitation on federal power.

Finally, even if the judgment were to somehow be viewed as consistent with Article III, there is still no statutory jurisdiction for entry of the "automatic" judgment. Because Bayer did not accuse Monsanto of infringing the three dismissed patents, the only potential statutory basis for such "automatic" judgment could be the Declaratory Judgment Act. However, in *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007), the Court reiterated that the Declaratory Judgment Act is available only in cases of adverse actual controversies:

> Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal

> interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

127 S.Ct. at 771 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). An interlocutory finding of inequitable conduct in a discrete proceeding does not create any controversy between the parties, much less one of any immediacy, so as to adjudicate the dismissed patents.

The "automatic" judgment is not supportable by the Declaratory Judgment Act and is not sustainable under Article III.

II. The Federal Circuit Extended Its Appellate Authority In Conflict with the Statutory Finality Requirement and with Decisions of This Court and Other Courts of Appeals

Because the district court lacked Article III jurisdiction to declare the dismissed patents unenforceable, the Federal Circuit should have vacated its holdings of unenforceability for lack of subject matter jurisdiction. But even if the Federal Circuit's view that 35 U.S.C. § 285 somehow conferred jurisdiction on the district court to adjudicate dismissed patents, it follows that there can be no final decision for appeal purposes until the court had rendered an adjudication under 35 U.S.C. § 285, the sole basis for the court's jurisdiction.

The Federal Circuit has exclusive appellate jurisdiction over patent cases, but only a "final decision of a district court" may be appealed. 28 U.S.C.

§ 1295(a)(1). With respect to the three dismissed patents, the sole issue before the district court was whether Monsanto was entitled to attorney fees under the "exceptional case" provision of 35 U.S.C. § 285. Therefore, only a judgment resolving the § 285 issues could be a "final decision" with respect to the three dismissed patents.

To be sure, 35 U.S.C. § 285 contemplates several steps. The first interlocutory step is that the trial court must first determine whether some material, inappropriate conduct has occurred; after which it determines whether that conduct renders the case "exceptional" and warrants an award of attorney fees. *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 653 (1983) ("With respect to attorney's fees, Congress expressly provided that a court could award such fees to a prevailing party only "in exceptional cases." 35 U.S.C. § 285"); *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 684 n. 15 (1999) (Stevens, J., dissenting) ("Attorney's fees are available only in 'exceptional' circumstances. 35 U.S.C. § 285. Once it has determined that the case is 'exceptional,' the district court has discretion whether or not to award attorney's fees and the fees 'must be reasonable.'") (citation omitted); *Brooks Furniture Mfg. v. Dutailier Int'l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005) ("A case may be deemed exceptional when there has been some material inappropriate conduct related to the matter in litigation, such as willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violates FED. R. CIV. P. 11, or like infractions.") (citations omitted); *Serio-US Industries,*

Inc. v. Plastic Recovery Technologies Corp., 459 F.3d 1311, 1321-22 (Fed. Cir. 2006). That a patent was inequitably procured does not necessitate a finding of "exceptional case" or award of attorney fees. *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1215 (Fed. Cir. 1987) ("it has not been held that every case of proven inequitable conduct must result in an automatic attorney fee award, or that every instance of inequitable conduct mandates an evaluation of the case as 'exceptional.'").

Here, with respect to the three dismissed patents, the district court's "final judgment", dated September 25, 2006, provided only that "U.S. Patents 5,254,799; 5,767,372 [and] 6,107,546 . . . are unenforceable due to Bayer's inequitable conduct during patent prosecution." (App. 64a) The final judgment did not address or adjudicate the merits of Monsanto's § 285 claim. That determination was made only upon further briefing and consideration, after which the district court finally entered its actual final decision as to the three dismissed patents: "Plaintiff Monsanto's Motion for a finding of exceptional case and for an award of attorney fees [doc. #898] is GRANTED." (App. 61a; 37a)

Accordingly, the district court's initial findings of inequitable conduct were but an initial step towards the final judgment under § 285. As such, they were interlocutory and not final decisions appealable under § 1295 until the district court entered its subsequent final § 285 determination and Judgment on April 12, 2007. Nevertheless, the Federal Circuit held that the former interlocutory order, which did not address the

statutory requirements of § 285, was the final decision in a matter where jurisdiction was founded solely under § 285.

The Federal Circuit's ruling improperly separated a judgment from its jurisdictional foundation. Nothing in 28 U.S.C. § 1295, or the parallel 28 U.S.C. § 1291, contemplates that "final decisions" may be anything other than the final judgments entered by the courts adjudicating the matters that provide the jurisdictional foundation for the court's proceedings.

The Federal Circuit's decision is breathtaking in its potential consequences to appellate jurisdiction. Congress has consistently restricted appellate jurisdiction to forbid piecemeal disposition of cases on appeal. *See Cobbledick v. United States*, 309 U.S. 323, 325 (1940). This Court has long held that an order is not final until it "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Catlin v. United States*, 324 U.S. 229, 233 (1945). As a result, the finality requirement does not permit appeals from decision that are "but steps towards final judgment in which they will merge." *Cohen v. Beneficial Industrial Loan Corp.*, 337 U.S. 541, 546 (1949).

If allowed to stand, this decision will thwart Congressional intent to promote efficient judicial administration by limiting the time, expense, and disruptive effect of patent appeals nationwide to those issues that remain once final judgment is reached. Moreover, it leaves patent litigants across the country without the certainty and predictability provided by the

final-judgment rule. The Federal Circuit's circular reasoning that a court, which had jurisdiction solely under § 285, could render a "final decision" before addressing and finally determining the statutory requirements of § 285, not only defies common sense and precedent, but creates a novel legal trap that litigants across the country will need to finesse by multiple appeals lest an interlocutory decision be deemed to be a sufficiently final judgment to start the time for appeal. Indeed, this decision places all patent litigants, like Bayer in this case, in the untenable position of possibly having their right to appeal foreclosed before final decision is even rendered by the district court. Moreover, given the common provisions of 28 U.S.C. §§ 1291 and 1295, and the number of fee-shifting statutes, this novel decision has far-reaching implications well beyond patent cases.

III. The Federal Circuit Grossly Misapplied Appellate Standards of Review

The Federal Circuit misapplied the fundamental appellate review standards, established by this Court and consistently followed by other Circuits, that once the appellate court finds clear error in the factual findings relied upon by the district court in reaching an ultimate legal determination, the appellate court should remand the case for further proceedings and not engage in its own fact-finding. In this case, the Federal Circuit effectively determined that the district court's single most critical fact finding — determining the materiality of a withheld document — was erroneous. However, rather than reversing or vacating the judgment and remanding, the Federal Circuit found a new basis for

materiality, following an approach that was never previously argued by any party or considered by the district court.

It is axiomatic that "'factfinding is the basic responsibility of district courts, rather than appellate courts,'" and that appellate courts should not resolve in the first instance factual disputes that have not been considered by the district court. *Pullman-Standard v. Swint*, 456 U.S. 273, 291-92 (1982) (quoting *DeMarco v. United States*, 415 U.S. 449, 450 (1974)); FED. R. CIV. P. 52(a). Indeed, this Court has long recognized that "[w]hen an appellate court discerns that a district court has failed to make a finding because of an erroneous view of the law, the usual rule is that there should be a remand for further proceedings to permit the trial court to make the missing findings." *Pullman-Standard*, 456 U.S. at 291.

For well over fifty years, this Court has consistently recognized that FED. R. CIV. P. 52(a), stating that "the court shall find the facts specially and state separately its conclusions of law thereon," also mandates remand where the district court fails to make specific findings of fact sufficient to support its conclusions. In *Kelley v. Everglades Drainage District*, 319 U.S. 415 (1943), this Court reiterated that "there must be findings, stated either in the court's opinion or separately, which are sufficient to indicate the factual basis for the ultimate conclusion." *Id.* at 422. While this requirement is designed to provide appellate courts with a clear understanding of the basis of trial courts' decisions and to aid trial courts in considering and adjudicating the

facts, see Wright & Miller, *Fed. Prac. & Proc. Civ.2d* § 2571 (2008), *Purcell v. Gonzalez*, 549 U.S. 1 (2006), and *United States. v. Merz*, 376 U.S. 192, 199 (1964), it also limits the authority of appellate courts when reviewing trial court decisions: "The reviewing court oversteps the bounds of its duty under Rule 52(a) if it undertakes to duplicate the role of the lower court. . . . '[A]ppellate courts must constantly have in mind that their function is not to decide factual issues *de novo*." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123 (1969).

The Court reaffirmed this approach most recently this term and emphasized the particular need for remand to the district court where, as here, the district court error arises as part of a decision generally left to the district court's discretion. In *Sprint/United Management Co.*, this Court held that by undertaking its own balancing under FED. R. EVID. 403 instead of remanding to the district court, the Tenth Circuit failed to "accord the District Court the deference we have described as the 'hallmark of abuse-of-discretion review.'" *Sprint/United Management*, 128 S. Ct. at 1145 (quoting *General Elec. v. Joiner*, 522 U.S. 136, 143 (1997)). Because determining if evidence is prejudicial under Rule 403 of the Federal Rule of Evidence is a fact-intensive and context-specific inquiry, this Court determined that:

> Rather than assess the relevance of the evidence itself and conduct its own balancing of its probative value and potential prejudicial effect, the Court of Appeals should have allowed the District Court to make these

> determinations in the first instance, explicitly and on the record.

Id. at 1146.

The ruling applies equally to a district court's determination of inequitable conduct. The determination of inequitable conduct is a fact-intensive, context-specific process. First, the district court must determine the materiality of the information claimed to have mislead the U.S. Patent and Trademark Office; second, it must ascertain whether the applicant had the requisite intent to deceive; and third, once materiality and intent to deceive have been established, the trial court "must 'weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred.'" *Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995)). In weighing materiality and intent, a high degree of materiality reduces the necessary degree of deceptive intent. *Honeywell Intern. Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 999 (Fed. Cir. 2007). Like a trial court's evidentiary rulings under FED. R. EVID. 403, a finding of inequitable conduct is reviewed for abuse of discretion because of the trial court's greater familiarity with the case and superior ability to (1) develop the factual record; (2) evaluate the credibility of witnesses as to the key facts; and (3) assess and weigh the degree of materiality against the facts relevant to intent.

The decision below was a clear departure from this Court's teachings regarding the abuse-of-discretion

standard of review. Here, the Federal Circuit rejected the district court's key finding that the handwritten notes disclosed the same gene Bayer was attempting to patent, thereby rejecting the district court's conclusion that the notes established a *prima facie* case of unpatentability under 37 C.F.R. § 1.56 (b)(1). In order to affirm the determination that the notes were material, the Federal Circuit considered new evidence and applied a different standard, set forth in 37 C.F.R. § 1.56 (b)(2)(i), to reach its own findings of materiality and intent:

> Since the notes meet the standard for materiality under § 1.56(2)(i) [*sic* § 1.56(b)(2)(i)], there is no clear error in the district court finding the notes material even though a part of the district court's opinion, viewed in isolation, suggests that it may also have reached that conclusion based on an untenable reading of the notes as stating that the Barnes Poster disclosed a gene coding for the same Bt toxin used by Bayer.

(App. 27a)

The new evidence analyzed by the Federal Circuit cannot be found in any arguments submitted by the parties or in the district court opinion. Instead, the Federal Circuit considered for the first time on appeal whether the notes were material under the inconsistent-argument standard of § 1.56(b)(2)(i). (App. 26a-27a) As a result, the Federal Circuit failed to give the district court the opportunity not only to consider these new facts under the different standard, but also to balance

the equities in light of the new standard and findings of materiality and intent in making the ultimate determination of inequitable conduct. This is particularly important here because a *prima facie* case of unpatentability under 37 C.F.R. § 1.56(b)(1), as erroneously found by the district court, is a more potent assessment than the "inconsistent argument" standard of 37 C.F.R. § 1.56(b)(2)(i) relied on by the Federal Circuit. This difference affects the balancing done in the first instance by the trial court to determine inequitable conduct, but the Federal Circuit merely presumed the ultimate conclusion would remain the same.

Unfortunately, the Federal Circuit's *sua sponte* materiality analysis exemplifies why remand is appropriate when an appellate court finds clear error in a material finding of fact: the Federal Circuit predicated its analysis on a fundamental misunderstanding of the patent prosecution record, which was not addressed in the district court opinion or by the parties on appeal because they were irrelevant to the district court's materiality standard. Bayer's only opportunity to argue and appeal this finding made for the first time in the Federal Circuit, is at the Supreme Court.

For example, in considering whether the handwritten notes were material under the standard of § 1.56(b)(2)(i) because they were inconsistent with a position Bayer took in asserting an argument of patentability, the Federal Circuit relied on prior and much broader patent claims for "a chimeric construct encoding any 60-80kD N-terminal fragment of a Bt toxin

protein." (App. 23a) But these claims had been abandoned and replaced with much narrower claims by the time Bayer made its arguments to the Patent Office regarding the Barnes poster presentation, on which the Federal Circuit relies.[4] (App. 23a-24a n.12) Accordingly, Bayer's argument for patentability in reference to the Barnes abstract was submitted to the Patent Office *after* Bayer had redrawn and narrowed its claims to a gene "which is expressed in plant cells comprising" a coding region encoding "a trypsin-digested Bt2 protein of SEQ. ID. No. 1." (*See*, the '565 patent, claim 1) Nevertheless, the Federal Circuit erroneously referenced these cancelled generic claims to conclude that the notes were "highly material" under 37 C.F.R. § 1.56(b)(2)(i). (App. 27a-28a)

By failing to remand, the Federal Circuit deprived the district court of the opportunity to decide in the first instance: (1) whether the notes were in fact inconsistent with the argument and, therefore, material in light of the patent claims as pending; (2) what degree of materiality should be assigned to the notes on this basis; and (3) whether this fact was a sufficient basis on which to infer fraudulent intent. The district court's superior ability to consider evidence and develop a record would likely have avoided the Federal Circuit's misreading of the record to erroneously conclude that the notes were

---

[4] The Federal Circuit recognized its factual mistake after Bayer filed its Petition for Rehearing and drew the error to the court's attention. Instead of remanding for the district court to analyze these new facts, the Federal Circuit attempted to rationalize its incorrect factual finding in an Errata Sheet. (App. 230a)

inconsistent with a patentability argument made with respect to patent claims that had previously been withdrawn. And if not, Bayer would have its right to appeal as an opportunity to clarify for the Federal Circuit.

The decision below conflicts with the decisions from the Second Circuit, *Fort Knox Music Inc. v. Baptiste*, 203 F.3d 193, 197 (2d Cir. 2000), Fourth Circuit, *O'Neal v. Gresham*, 519 F.2d 803, 805 (4th Cir. 1975), Fifth Circuit, *Corpus Christi Taxpayer's Ass'n. v. City of Corpus Christi*, 858 F.2d 973, 977 (5th Cir. 1988), Seventh Circuit, *Jones v. Jones Bros. Constr. Corp.*, 879 F.2d 295, 297 (7th Cir. 1989), Eighth Circuit, *Duffie v. Deere & Co.*, 111 F.3d 70, 73-74 (8th Cir. 1997), Ninth Circuit, *Security Farms v. International Bhd. of Teamsters*, 124 F.3d 999, 1015-1016 (9th Cir. 1997), Tenth Circuit, *OCI Wyo., L.P. v. PacifiCorp*, 479 F.3d 1199, 1206 (10th Cir. 2007), and Eleventh Circuit, *Keefe v. Bahama Cruise Line, Inc.*, 867 F.2d 1318, 1323 (11th Cir. 1989), all of which have vacated judgments and remanded to the district court for further proceedings if a district court failed to make the appropriate findings on a material issue.

As the Eight Circuit explained in *Duffie v. Deere & Co.*, 111 F.3d 70, 73-74 (8th Cir. 1997):

> Since the underlying factual finding is clearly erroneous, we think it procedurally judicial to remand the case to the district court to decide again the ultimate issue . . . , making further

> factual findings to support its determination. For us to proceed to the ultimate issue of disability with no factual findings as our basis would violate this court's function, which is to review, rather than to make, findings of fact.

In direct conflict with this approach, the Federal Circuit misapplied the distinction between (a) supporting a trial court's material findings of fact that are correct but improperly analyzed under the law, and (b) substituting its judgment in an essential fact-finding exercise by selecting new facts to affirm the district court's ultimate conclusion, previously reached on clearly erroneous facts. *See, e.g., Pullman-Standard*, 456 U.S. 273. The former approach is appropriate and, like a clarification on proper application of the law, it allows the appellate court to correct a trial court's misunderstanding as to why a particular fact is material under the appropriate legal standard. *Pullman-Standard*, 456 U.S. at 291-92. In contrast, the latter approach usurps the fact-finding role of, and fails to give appropriate deference to, the superior ability of the trial court to find facts and weigh the equities in the first instance, after correction of a clearly erroneous premise.

If allowed to stand, this approach contravenes the teachings of this Court, other Circuits and FED. R. CIV. P. 52(a), and elevates the Federal Circuit as the superior fact finder in patent cases, at least in regard to questions of inequitable conduct. Because the Federal Circuit is the exclusive appellate venue for patent cases decided by all United States district courts, it is important that this Court correct this error.

CONCLUSION

Petitioner respectively requests that this Petition for Certiorari be granted.

Dated: July 16, 2008

Respectfully submitted,

GEORGE PAZUNIAK
Counsel of Record
JAMES LENNON
ANNAMARTINA TYREUS
WOMBLE CARLYLE SANDRIDGE
& RICE, PLLC
222 Delaware Avenue
Suite 1501
Wilmington, DE 19801
(302) 252-4320

VIRGINIA W. HOPTMAN
WOMBLE CARLYLE SANDRIDGE
& RICE, PLLC
8065 Leesburg Pike
Suite 401
Tysons Corner, VA 22182
(703) 790-3310

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED APRIL 23, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1299

MONSANTO COMPANY,

Plaintiff-Appellee,

v.

BAYER BIOSCIENCE N.V.,

Defendant-Appellant.

DECIDED: April 23, 2008

Before BRYSON, GAJARSA, and LINN *Circuit Judges.*

PER CURIAM.

In 2000 Plaintiff-Appellee Monsanto Co. ("Monsanto") brought a declaratory judgment action against Defendant-Appellant Bayer Bioscience N.V. ("Bayer") challenging the validity and unenforceablity of four Bayer patents, U.S. Patent Nos. 5,545,565 ("the '565 patent"), 5,767,372 ("the '372 patent"), 6,107,546 ("the '546 patent"), and 5,254,799 ("the '799 patent"), and asserting that Monsanto's transgenic corn products did not infringe these patents. The case is now before us for the third time. For the reasons stated below, we *affirm.*

Most recently, in Appeal No. 2007-1109, Bayer appealed the final judgment issued after jury trial and a bench trial declaring the asserted claims of the '565 patent invalid and non-infringed, and holding all four patents unenforceable for inequitable conduct. *Monsanto v. Bayer Bioscience N.V.*, 514 F.3d 1229 (Fed.Cir.2008) (*Monsanto III*). A panel of this court affirmed on the grounds that the district court did not err in holding the four patents unenforceable for inequitable conduct. We upheld the inequitable conduct ruling with regards to the '565 patent because there was no clear error in the district court finding Bayer failed to disclose material information regarding the '565 patent with an intent to deceive the PTO during the prosecution of the patent. *Id.* at 1241-42. In addition, we rejected Bayer's arguments that the district court was without jurisdiction to declare the '372, '546, and '799 patents unenforceable for inequitable conduct. *Id.* at 1242-43. In light of Bayer's failure to challenge the merits of the district court's inequitable conduct findings regarding these three patents, we therefore also affirmed the district court's inequitable conduct findings for these patents. *Id.* at 1243 n. 18 ("Bayer does not, in this appeal, challenge the district court's findings of inequitable conduct regarding the '799, '372, and '546 patents. Therefore, those findings are affirmed."); *see Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed.Cir.1999) ("An issue that falls within the scope of the judgment appealed from but is not raised by the appellant in its opening brief on appeal is necessarily waived.").

Appendix A

In the current appeal, Bayer appeals the final judgment of the district court granting attorney fees to Monsanto under 35 U.S.C. § 285. The district court concluded that attorney fees were warranted because Bayer's inequitable conduct in the prosecution of the four patents made the case exceptional. *See* 35 U.S.C. § 285 (allowing for award of attorney's fees in "exceptional cases"); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed.Cir.2001) (holding that a party may prove the existence of an exceptional case by showing inequitable conduct before the PTO).

Whether a case is exceptional under § 285 is a factual question reviewed for clear error. *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1460 (Fed.Cir.1998). The district court's decision to award attorney fees after finding a case exceptional is reviewed for abuse of discretion. *Id.* In the instant case, Bayer does not challenge the discretionary determination to award attorney fees. Rather, Bayer argues only that the district court erred in finding that each of the four patents was procured through inequitable conduct.

The law of the case "prevent[s] the relitigation of issues that have been decided" absent narrow exceptional circumstances. *Gould, Inc. v. United States*, 67 F.3d 925, 930 (Fed.Cir.1995) (quoting *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 839 F.2d 1544, 1550 (Fed.Cir.1998)). Under the law of the case doctrine "a court adheres to a decision in a prior appeal in the same case unless one of three exceptional circumstances exist: (1) the evidence in a subsequent trial is substantially

different; (2) controlling authority has since made a contrary decision of the law applicable to the issues; or (3) the earlier ruling was clearly erroneous and would work a manifest injustice." *Id.*

Bayer already appealed the district court's judgment that all four patents were unenforceable for inequitable conduct in the 2007-1109 appeal, and in the disposition of that appeal this court explicitly affirmed the district court's findings that there was inequitable conduct in the prosecution of each of the four patents. *Monsanto III*, 514 F.3d at 1241-42,1243 n. 18. As none of the exceptions to the law of the case applies, we cannot revisit our prior holding. Bayer has presented no other argument for reversing the district court's grant of attorney's fees. Accordingly, the judgment of the district court is affirmed.

Costs to Appellee.

APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED JANUARY 25, 2008 AS AMENDED BY ERRATA JANUARY 25, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 2007-1109

MONSANTO COMPANY,

Plaintiff-Appellee,

v.

BAYER BIOSCIENCE N.V.,

Defendant-Appellant.

Rehearing and Rehearing En Banc Denied April 17, 2008

Jan. 25, 2008

Before BRYSON, GAJARSA, and DYK, Circuit Judges.

GAJARSA, *Circuit Judge.*

This is a patent infringement case relating to chimeric genes. Plaintiff-Appellee Monsanto Co. ("Monsanto") brought a declaratory judgment action

against Defendant-Appellant Bayer Bioscience N.V. ("Bayer") challenging the validity and unenforceability of four Bayer patents, U.S. Patent Nos. 5,545,565 ("the '565 patent"), 5,767,372 ("the '372 patent"), 6,107,546 ("the '546 patent"), and 5,254,799 ("the '799 patent"), and asserting that Monsanto's transgenic corn products did not infringe these patents. Bayer appeals a final judgment, issued after jury trial, declaring the asserted claims of the '565 patent invalid and non-infringed. In addition, Bayer appeals the final judgment of the district court that the four patents are unenforceable for inequitable conduct. We affirm the district court's conclusion that the '565 patent is unenforceable for inequitable conduct and hold that the district court had jurisdiction to declare the '372, '546, and '799 patents unenforceable. Accordingly, we do not reach the other issues raised by Bayer on appeal.

I.

Strains of the bacteria *Bacillus thuringiensis* ("Bt") produce proteins, known as Bt toxins, that while harmless for humans and most animals, are toxic to certain crop-destroying insects. In the 1980s multiple companies and academic groups took advantage of the newly emergent science of genetic engineering by attempting to insert a gene for Bt toxin into plants through a process known as transformation. The goal was for these genetically engineered plants to express (i.e., produce) a Bt toxin protein in sufficient quantities

to make the plants insect-resistant.[1] Difficulties in getting plants to express a full-length Bt toxin gene, which encodes a protein of approximately 130 kD,[2] led researchers to investigate various alternatives. In 1986, Plant Genetic Systems, N.V., a predecessor of Bayer (hereinafter referred to as "Bayer"), succeeded in obtaining plants that expressed a truncated form of a Bt toxin. This shortened protein was produced by transforming the plants with a fragment of a Bt toxin gene that encoded the first part (or N-terminal end) of the toxin, using the bacterium *Agrobacterium tumefaciens* ("*Agrobacterium*"), a known system for plant transformation.[3]

---

1. Background on the science of genetically engineering plants to express Bt toxin can be found in our previous opinion *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1324 (Fed.Cir.2001).

2. kD, or kilodalton, is a measure of the molecular weight of a protein.

3. When *Agrobacterium* infects certain plant cells, it integrates a part of its DNA, the T-DNA plasmid, into the genome of the plant. To genetically engineer a plant using the *Agrobacterium* transformation method, the foreign DNA of interest is first introduced into the T-DNA plasmid. Then the plant is infected with *Agrobacterium* containing the modified T-DNA, leading to the introduction of the foreign segment into the plant cell genome. *See In re Goodman*, 11 F.3d 1046, 1048 (Fed.Cir.1993). When the encoding region of the foreign gene is linked to a regulatory region recognized by the plant cell machinery, the transformed plant cell will be able to express the protein encoded by the foreign gene.

Appendix B

The four patents involved in the present suit relate to this invention. The '565 patent claims chimeric genes[4] comprising (a) a truncated Bt toxin gene encoding an approximately 60 kD to 80 kD Bt toxin of a specific amino acid sequence,[5] and (b) the regulatory region of a gene "naturally expressed in plant cells,"[6] which enables the gene to be transcribed in plants, i.e., a "plant promoter," where the Bt toxin gene is under the control of the plant promoter.[7] The '372 patent, '546 patent, and the '799

---

4. A chimeric gene is an artificial (i.e., human made) gene created by linking together separate segments of natural or synthetic DNA from different sources.

5. Not all Bt toxins have identical amino acid sequences. The sequence limitation, added during the prosecution to overcome rejection, limits Bayer's invention to chimeric genes encoding a specific variant of Bt toxin, of the Bt2 class of toxins.

6. The specification defines a gene naturally expressed in plants to include both those genes that are originally part of a plant's genome and those genes which are introduced by agents such as bacteria and produce RNA or protein in the absence of human intervention. '565 patent col.9 ll. 52-57. One plant promoter disclosed in the specification is the promoter of the T-DNA nopaline synthase gene, the "nos promoter."

7. Claims 2, 5, and 8 of the '565 patent were at issue, with claim 5 being representative. In independent form it recites:5. A chimeric gene comprising:

> (1) a DNA fragment encoding an insecticidal Bacillus thuringiensis Bt2 toxin of about 60 to about 80 kD, wherein said Bt2 toxin comprises the amino

(Cont'd)

patent are directed towards various other aspects of the technology including plant cells and plants that produce the insecticidal protein, and methods of transforming plants with the chimeric genes.

Monsanto sells a genetically modified corn product MON810 that expresses a Bt toxin with the same amino acid sequence claimed by Bayer. In December 2000, Monsanto filed a declaratory judgment action in the Eastern District of Missouri seeking a declaration that its product did not infringe the '565, '372, '546, and '799 patents and that these patents were invalid and unenforceable. Bayer counterclaimed alleging infringement of certain claims in each patent. The district court initially granted summary judgment to Monsanto, holding that all four patents were unenforceable due to inequitable conduct, that certain patent claims were invalid, and that the '565 patent was not infringed. Bayer appealed to this court. We reversed the trial court's claim construction as to the term "Bt2 toxin" and vacated the unenforceability and invalidity

---

(Cont'd)

> acid sequence ID No. 1 from amino acid position 1 to amino acid position 725; and (2) a promoter region of a gene naturally expressed in plant cells, wherein said DNA fragment is under the control of said promoter region.

'565 patent col.115. Dependent claim 12 adds a limitation that the plant promoter come from one of three genes, including the nopaline synthase gene. *Id.*

judgments. *Monsanto Co. v. Bayer BioScience N.V.*, 363 F.3d 1235 (Fed.Cir.2004) (*Monsanto I*). In particular, we held that the summary judgment of unenforceability based on inequitable conduct during the prosecution of the '799 patent was improper because there were material facts in dispute, and we concluded that the district court erred in giving collateral estoppel effect to an earlier case between predecessors of the parties in this case and basing its invalidity findings on this estoppel.

On remand, Bayer dismissed all claims that MON810 infringed the '799, '372, and '546 patents and filed a Statement of Non-Liability as to these patents. Accordingly, when the case proceeded to trial, only the '565 patent was at issue. The jury found the asserted claims of the '565 patent not infringed and invalid for obviousness and prior invention by Monsanto.

Subsequently, the district court held a four-day bench trial on inequitable conduct. In a 99-page opinion, the district court found materiality and intent for two separate acts relating to the '565 patent and concluded that inequitable conduct made the '565 patent unenforceable. *Monsanto v. Bayer BioScience N.V.*, No. 400cv01915, slip. op. (E.D.Mo. Aug. 28, 2006) (*Monsanto II*). The court also found inequitable conduct in the prosecution of the '799, '372, and '546 patents and accordingly held these patents unenforceable. *Id.* at 95. Bayer appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

Appendix B

In the current appeal, Bayer argues that the district court erred in claim construction, that allegedly prejudicial evidence was admitted during the jury trial, that there was insufficient evidence to sustain the jury findings of prior invention and obviousness, that the district court erred in finding the '565 patent unenforceable for inequitable conduct, and that the district court lacked jurisdiction to find the '799, '372, and '546 patents unenforceable.

Because we affirm the district court's holding that the '565 patent is unenforceable for inequitable conduct, we need not reach the other issues raised by Bayer relating to the jury findings of invalidity and non-infringement of the patent. *See eSpeed, Inc. v. Brokertec USA L.L.C.*, 480 F.3d 1129, 1138-39 (Fed.Cir.2007). Accordingly, we review only the district court's inequitable conduct holdings.

II.

When this Court reviews an inequitable conduct determination, "[w]e review the district court's findings on the threshold issues of materiality and intent for clear error." *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1365 (Fed.Cir.2007). Accordingly, "the district court's determination will be reversed only if there is a 'definite and firm conviction' that a mistake has been made." *Id.* The ultimate decision on inequitable conduct is reviewed for abuse of discretion. On appeal, Bayer does not challenge the ultimate discretionary determination. Therefore, we review here only whether there was clear

error in the district court's underlying materiality and intent findings.

To hold a patent unenforceable for inequitable conduct, a district court must find by clear and convincing evidence that a patent applicant breached its duty of candor and good faith to the United States Patent and Trademark Office ("PTO") by failing to disclose material information, or submitting false material information, with an intent to deceive the PTO. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1351 (Fed.Cir.2005); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed.Cir.1988) (internal citations omitted); *see also Monsanto I*, 363 F.3d at 1239 (explaining that inequitable conduct can be found when the "applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner"). Once the requisite levels of materiality and intent have been proven, a district court "must balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable." *Monsanto I*, 363 F.3d at 1239.

A.

During the prosecution of the '565 patent, Bayer disclosed as prior art an abstract by Dr. Wayne Barnes entitled "A Bifunctional Gene for Insecticide and Kanamycin Resistance" (the "Barnes Abstract") that had been prepared in 1985 for a large scientific conference at which Barnes had made a presentation

by displaying a poster presenting his findings (the "Barnes Poster"). The abstract read, in relevant part:

> We have found that the second half of the Bacillus thuringiensis toxin gene is dispensable for the expression of an active insecticide. Not only may it be deleted, the second half of the gene may be replaced by the codons of the NPTII kanamycin resistance from Tn5, and both activities are expressed. . . .
>
> We have tailored transcriptional control signals from the [*Agrobacterium*] T-DNA of pTiT37 so that this fused gene may be inserted in the place of the nopaline synthase codons adjacent to the right border signal from T-DNA. This plant gene should express the insecticide and kanamycin resistance from the same promoter. . . .

Bayer's application, as amended following an initial rejection, claimed any chimeric gene comprising a plant promoter linked to a truncated Bt toxin gene encoding a 60-80 kD N-terminal fragment of a Bt toxin, in which the chimeric gene could be expressed in the cell as an insect-controlling amount of Bt toxin. Narrower, dependent claims, akin to the claims that ultimately issued, specified that the chimeric gene must encode a

BEST AVAILABLE COPY

Bt toxin with a specified amino acid sequence.[8] In addition, the application claimed chimeric genes encoding the Bt toxin fragment fused to a selectable marker protein. Dependent claims included limiting the selectable marker protein to neomycin phosphotransferase ("NTP-II"), an enzyme that provides resistance to the antibiotic kanamycin, and limiting the "plant promoter" to the nos promoter, which is the promoter region from the T-DNA nopaline synthase gene.

On March 21, 1994, the Examiner rejected all claims, including the sequence specific claims, as obvious over various prior art references including the Barnes Abstract. In particular, the Examiner noted that the Barnes Abstract

> provided motivation to genetically engineer plant cells with a truncated Bt crystal gene rather than using the full length sequence. In the absence of unexpected results it was obvious that a truncated version of the Bt crystal protein would result in plants and plant

---

8. The claims which ultimately issued as the '565 patent differ from these preliminary claims, even those that are sequence specific, in that they do not require that the Bt toxin be expressed in plant cells at an insect-controlling amount, but only that the Bt toxin gene be "under the control of" the plant promoter. Bayer did not object to the district court's holding and jury instruction that reduction to practice of the '565 invention did not require making plants which expressed an insecticidal Bt toxin.

> cells which were insecticidal since the art taught that only the N-terminal protein of the Bt protein, i.e. the portion used by Applicants, was sufficient for insecticidal activity. Furthermore, fusion proteins for truncated Bt. crystal proteins with NPT-II were known as taught by Barnes.

The claims were also rejected for lack of enablement. The Examiner noted that the prior art showed that "expression of [Bt] toxin genes in a plant cell is highly unpredictable" and concluded that "[i]n view of the unpredictability of expression of foreign genes . . . it does not appear that any Bt toxin protein would be effective in plant cells against any species of insect. Consequently, Applicants broader claims are not enabled."

In reply to the office action, Bayer canceled its broadest claims and addressed both rejections. In order to overcome the Barnes reference, Bayer argued:

> Barnes et al. fails to identify which *Bt.* toxin gene should be utilized and also fails to show that the fusion gene would work in plants. Also, if the "second half" of the *Bt2* gene would be deleted, as Barnes et al. suggests, the remaining part would encode a protein of 576 amino acids, which is not toxic. Moreover, the Barnes et al. reference is not enabled since it is stated therein that the fused gene "may" be inserted into T-DNA and that the plant

> gene "should" express the insecticide and kanamycin resistance from the same promoter. But no concrete evidence is provided.

On the enablement issue, Bayer argued that "[t]he problem of the unpredictability of expression of foreign genes in plants, that the Examiner purports to exist, has *actually been solved by the present invention* by providing truncated Bt genes. Any protein expressed in a plant, by inserting a DNA encoding a truncated Bt protein will inherently possess toxicity . . . , and thus the plants will be toxic to target insects." (emphasis added).

Although Bayer disclosed the Barnes Abstract during patent prosecution, it did not disclose the notes taken by one of its employees, Dr. Celestina Mariani, regarding the Barnes Poster, to which the abstract was in reference, nor the information contained in the notes. Mariani had attended the conference and personally viewed Barnes' poster. She explained in her deposition, which was presented at trial, that the notes were made while in front of the poster and included copies of "the same schemes that were presented on the poster." *Monsanto II*, slip op. at 19 (quoting Mariani's deposition testimony ("Mariani depo.")). The poster contained much more information than the abstract itself. *Id.* at 24. In the deposition, Mariani carefully and extensively described the content of her handwritten notes. Stepping through the figures and accompanying text, she explained that her notes illustrated that Barnes

disclosed in his poster that he had (a) truncated a 3.4 kB Bt toxin gene[9] at or near the restriction enzyme site xho and discovered that this gene fragment encoded a N-terminus 67 kD truncated Bt toxin which retained toxicity; (b) created a chimeric gene which encoded a fusion of this truncated Bt toxin protein and the NPT-II protein; (c) expressed this fusion protein in a bacterial system and demonstrated that the expressed protein provided kanamycin resistance and was toxic to insects when applied to plants "in drops"; and (d) inserted the gene for this fusion protein into an *Agrobacterium* T-DNA plant expression vector, creating a chimeric gene comprising the nos promoter, the Bt toxin gene fragment encoding a 67 kD toxin, and the NPT-II gene. *Id.* at 19-24 (quoting Mariani depo.). Mariani's notes also stated that the chimeric construct was "not toxic if it is in leaves." *Id.* at 22 (quoting Mariani depo.). She explained in her deposition, "I must assume that 'in leaves' then means they have done plant transformation, but I cannot remember exactly, to be honest." *Id.* at 22 (quoting Mariani depo.). But she emphasized that the construct had been created and that the Barnes group "surely w[as] busy with introducing in plants this cassette" since otherwise there would have been no reason to make the construct in the *Agrobacterium* T-DNA system. *Id.* at 24 (quoting Mariani depo.). The district court found that Mariani's testimony demonstrated that she remembered "a great deal about the notes" and was

---

9. kB, or kilobases, is a unit of length equal to 1000 base pairs of DNA. The Bt2 toxin gene Bayer was using was also approximately 3.4 kB.

clearly and articulately able to describe the contents of the Barnes Poster as detailed in the notes. *Id.* at 18.[10]

The Mariani notes were "widely circulated" among Bayer's Bt group. Dr. Wouter Meulemanns worked in the intellectual property department at Bayer and was responsible for the prosecution of the four patents at issue. *Id.* Meulemanns admitted that he saw Mariani's notes during the prosecution of the '565 patent and remembers talking to Mariani about the Barnes Poster and her notes. He conceded that "if [the Mariani] notes would add anything of reliable information which could add to the abstract, that could be important" to a patent examiner. *Id.* at 17-18 (quoting Meulemanns depo.). However, Meulemanns stated that Mariani was unable to remember "anything" about the presentation or poster during their conversation.

The district court, in its memorandum and order following the inequitable conduct bench trial, carefully reviewed all of this evidence, quoting extensively from the testimony of both Meulemanns and Mariani. The court found Meulemanns' testimony to stand in "sharp contrast" to Mariani's detailed deposition testimony and determined that Meulemanns was not credible in claiming not to have known nor understood the content of the notes despite having discussed them with

---

10. At trial Mariani was much less forthcoming about the content of her notes than she had been in the deposition. The district court, however, found her initial deposition testimony more credible. *Monsanto II*, slip op. at 97. There is nothing clearly erroneous in this credibility finding.

Mariani. And after quoting at length from Dr. Mariani's deposition testimony, the district court concluded:

> [I]t is very obvious that the poster notes, if they were disclosed to the patent examiner, which they were not, would stand in sharp contradiction to the Bayer argument before the patent examiner. . . . The Court finds from all of the evidence in the case, that Bayer had a duty of candor and good faith to disclose the Mariani notes and intentionally withheld the information from the United States Patent Office examiner in the prosecution of the '565 patent with intention to deceive the PTO examiner.

Id. at 24.

These findings were made in the section of the district court's opinion entitled "Findings of Fact." In the section entitled "Discussion" the district court returned to the question of the materiality of the Mariani notes. The court explained:

> The Court will not repeat the lengthy Mariani recitation from above, but it is clear that the Barnes notes coded for the same 67 Kd toxic protein Bayer wanted to claim, that the Barnes gene was 3.4 kb for the full length, that because of the identified xho site, it would be easy to determine the identity of the Bt gene being used, and the chimeric gene used was

> toxic to insects by the drop. There is a substantial likelihood that a reasonable examiner would have considered the Barnes notes important in deciding whether to allow the application to issue as a patent. . . . The Barnes notes by themselves withheld by Bayer from the PTO examiner, if disclosed, would establish a prima facie case of unpatentability of Bayer's claims under the '565 patent.

Id. at 97-98. Accordingly, the court concluded that "by clear and convincing evidence for all of the reasons cited in this opinion," Bayer made "a deliberate decision to withhold the known highly material reference with the specific intent to deceive or mislead the PTO examiner." *Id.* The court emphasized that in reaching this determination, it was relying on "all of the findings of fact stated in this opinion," not just those in the discussion section. *Id.* at 92.

The district court also found by clear and convincing evidence that Bayer's representation to the PTO that unpredictability of gene expression had been solved was false and misleading and was submitted to the PTO examiner with the specific intent to deceive the PTO. *Id.* at 96.

Appendix B

B.

Information is material for the purposes of an inequitable conduct determination if " 'a reasonable examiner would have considered such [information] important in deciding whether to allow the parent application.' " *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed.Cir.2006) (quoting *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1363 (Fed.Cir.2003)). "In evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56." *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1129 (Fed.Cir.2006). Rule 56 defines material information as:

> information that is not cumulative to information already of record or being made of record in the application, and that
>
> (1) establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) . . . refutes, or is inconsistent with, a position the applicant takes in:
>
> > (i) Opposing an argument of unpatentability relied on by the Office, or
> >
> > (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. A misstatement or omission that is material under the Rule 56 standard is considered material for the purposes of the inequitable conduct inquiry. *Digital Control Inc.*, 437 F.3d at 1316.[11]

Bayer argues that the "sole basis" for the district court's determination that the Mariani notes were material was the conclusion in one sentence of the discussion section that the Barnes construct "coded for the same 67 kD toxic protein Bayer wanted to claim" and "that because of the identified xho site it would be easy to determine the identity of the Bt gene being used." Bayer argues that these findings were clearly erroneous because they were based on the unsupported speculation that Barnes was using the identical species of Bt toxin as Bayer, and that without this "erroneous finding of fact, there can be no materiality." We disagree.

To begin, Bayer is correct that there is nothing in the record which would support a finding that the Bt toxin used by Barnes was identical to the Bt toxin

---

11. Although all misstatements or admissions that satisfy Rule 56 are considered material, the converse is not true: A misstatement or admission can be material for the purposes of showing inequitable conduct even if it does not meet the standard for Rule 56 if, in the totality of the circumstances, a reasonable examiner would have considered such information important in deciding whether to allow the parent application. *See Digital Control Inc.*, 437 F.3d at 1316 ("[I]f a misstatement or omission is material under the new Rule 56 standard, it is material. Similarly, if a misstatement or omission is material under the 'reasonable examiner' standard or under the older three tests, it is also material.").

claimed in the issued '565 patent. However, the district court need not have found that Barnes used the identical Bt toxin as Bayer for the Mariani notes to be material. First, at the time of the Examiner's rejection, Bayer was not limiting its claim to one species of Bt toxin protein but was broadly claiming a chimeric construct encoding any 60-80 kD N-terminal fragment of a Bt toxin protein. Thus, any species of chimeric gene created by Barnes within this genus would directly implicate the allowability of Bayer's claims. *Cf. Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 971 (Fed.Cir.2001) (noting that a "genus claim limitation is anticipated by, and therefore not patentably distinct from, a[ ] . . . species claim"). Second, none of the Examiner's rejections, including his rejections of the sequence specific claims, nor any of Bayer's arguments to overcome these rejections, relied on the exact sequence of Bt toxin used by Barnes. Rather, the issue was whether the Barnes Abstract made Bayer's invention obvious absent unexpected results because Barnes' work with Bt toxin, regardless of the specific species used, provided motivation to genetically engineer plant cells with "a truncated Bt crystal gene" and "taught fusion proteins of truncated Bt crystal proteins with NPT-II." Similarly, the exact sequence of the Barnes protein is irrelevant to the question of whether Bayer's arguments to the PTO interpreting the Barnes Abstract were inconsistent with the information contained in the Mariani notes.[12]

---

12. Indeed, despite having canceled the broader claims 'solely to expedite the prosecution of th[e] application, and not to acquiesce to the rejection,' at the time Bayer distinguished

(Cont'd)

Moreover, Bayer is incorrect that the "sole basis" for the district court's materiality finding was the court's one sentence summary that the Barnes construct coded for the "same 67 kD protein" as Bayer claimed, and the xho site would make it easy to identify. Bayer ignores that the very sentence in the analysis section containing these two statements also repeats the court's critical finding that the Mariani notes showed that the Barnes chimeric gene was toxic when applied to plants as a drop.[13] Furthermore, the district court clearly stated

---

(Cont'd)

Barnes, it was continuing to argue that its disclosure of a chimeric gene with one version of a truncated Bt gene was sufficient to enable the genus of all chimeric genes with any truncated Bt toxin gene. *See* Response to Office Action (Sept. 28, 1994) ("Any Bt protein expressed in a plant, by inserting a DNA encoding a truncated Bt protein will inherently possess toxicity characteristics against its target insect, and thus the plants will be toxic to target insects. It is well within the skill of the person in the art to select a particular Bt protein gene with an observed toxicity to a target insect, truncate the gene and express it to attain resistance against the target insect."). Bayer can therefore not now argue that only those prior art references disclosing the particular Bt toxin described in the specification can be material.

13. In its opening brief to this court and again in its reply brief, Bayer's quotation of the sentence of the district court's opinion upon which it places primary reliance leaves out this important final clause of the sentence and, by failing to use ellipses, makes it appear that it has quoted the entire sentence. Such misquotation of text, whether inadvertent or purposeful, risks misleading this Court and cannot be of help to the client.

that it was basing its finding of materiality not only on those facts discussed in the analysis section, but also on all the factual findings throughout the opinion.[14] These included finding Mariani's deposition testimony credible and illustrative of the "detail and scope of her notes and of her recollection of them." And the district court incorporated six pages of Mariani's testimony verbatim into its opinion. This testimony established that the Barnes Poster, as recorded in Mariani's notes, disclosed that Barnes had succeeded in making a fusion of the first 67 kD of a Bt protein and NPT II; that this protein could be expressed and displayed *kanamycin* resistance and toxicity to insects when applied as a drop; and that the gene encoding for this fusion protein had been inserted into a T-DNA plasmid, creating a chimeric gene comprising a plant promoter, the truncated Bt toxin gene, and the NPT-II gene. Based on Mariani's testimony, the district court found it "very obvious" that the poster notes would stand in "sharp contradiction" to Bayer's argument before the patent examiner, in which Bayer argued that the construct described in the Barnes Abstract was non-toxic and non-enabled.

We see no clear error in these findings. The undisputed evidence established that the arguments Bayer made to the Examiner to overcome the rejection based on the Barnes Abstract cannot be reconciled with the information about the Barnes Poster disclosed in

14. Accordingly, we need not decide whether if the facts repeated in the analysis section had been the only basis for a finding of materiality the district court's finding would constitute clear error.

BEST AVAILABLE COPY

the Mariani notes. First, Bayer argued to the Examiner that he should read the Barnes Abstract's statement that the "second half" of the Bt toxin gene is dispensable literally, as referring to a gene of exactly half the length of the full length gene, which for the Bt2 gene would encode a 576 amino acid protein, a size smaller than 67 kD and known to be too small to be toxic. This was perhaps a plausible, if strained, reading of the Abstract itself. But the interpretation cannot be reconciled with the additional information disclosed about the Barnes Poster in the Mariani notes. Mariani's notes demonstrated that the truncated protein referred to in the abstract was a 67 kD protein with proven insect toxicity. Second, Bayer relied on the use of the word "may" in the Abstract to argue that Barnes had not enabled inserting the Bt toxin/NPT-II fusion gene into *Agrobacterium* T-DNA because there was no "concrete evidence" that the construct had been made. In contrast, the Mariani notes disclosed that Barnes had in fact created the described T-DNA construct.

In light of these discrepancies between the interpretation of the Barnes Abstract Bayer advocated and the information contained in the Mariani notes, the Mariani notes clearly and convincingly "refute[ ], or [are] inconsistent with," a position the applicant took in opposing the Examiner's argument of unpatentability. 37 C.F.R. § 1.56(2)(i). The notes are therefore material under 37 C.F.R. § 1.56(2)(i). *See also Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed.Cir.2003) ("[M]ateriality is not limited to prior art but embraces *any* information that a reasonable

examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent." (quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed.Cir.2001))).[15] Since the notes meet the standard for materiality under § 1.56(2)(i), there is no clear error in the district court finding the notes material even though a part of the district court's opinion, viewed in isolation, suggests that it may also have reached that conclusion based on an untenable reading of the notes as stating that the Barnes Poster disclosed a gene coding for the same Bt toxin used by Bayer. There is a substantial likelihood that a reasonable examiner would have considered the Mariani notes important in deciding whether to allow the application to issue.

We hold that the Mariani notes are material because they directly contradict arguments Bayer made to the PTO in support of patentability. We do not suggest that all internal documents of potential relevance must be submitted to the PTO as a matter of course. Rather, it is the particular circumstances that render the internal documents material in this case. We need not decide

---

15. That the Mariani notes may have required some explanation by Mariani to be fully understood does not alter their materiality. Rather, it is the information contained in them that makes the notes material and which Bayer, in light of its interpretation of the Barnes Abstract, had an obligation to communicate to the PTO. If an accompanying declaration by Mariani was necessary to make the notes legible, then the duty of candor would require disclosing both the notes and such a declaration.

whether, as the district court found, they are also material because the notes by themselves would establish a prima facie case of unpatentability of the *'565 patent's* claims. But certainly their materiality is augmented by the fact that Mariani's notes demonstrate, in significantly more detail than the Barnes Abstract, that Barnes had already disclosed that a 67 kD N-terminal fragment of a Bt toxin protein retained toxicity either alone or fused to a NPT-II protein and taught a chimeric gene comprising the 67 kD Bt toxin gene and a plant promoter. Bayer was attempting to claim a nearly identical invention-a chimeric gene comprising a gene encoding a 60 to 80 kD Bt toxin protein and a plant promoter. Accordingly, we affirm the district court's finding that the Mariani notes were highly material.[16]

---

16. In Bayer's reply brief, Bayer argues for the first time that even if its other arguments fail the Mariani notes lack materiality because they would have been "merely cumulative" in light of the prior art reference of a *Gene* article by Dr. Adang which "disclosed toxic genes encoding Bt proteins of about 67-68 kd." We do not consider this argument as it has been waived. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed.Cir.1990) ("[A]n issue not raised by an appellant in its opening brief . . . is waived."). Even if we were to reach the issue, Bayer's argument ignores that the materiality of the Mariani notes is based not only on the size of the protein disclosed in her notes, but also on the notes' disclosure that Barnes had constructed a chimeric gene containing a 67 kD fragment of a Bt toxin gene fused to a kanamycin resistance gene attached to a plant promoter. Bayer overcame the Adang

(Cont'd)

Appendix B

C.

Bayer's failure to disclose the highly material Mariani notes to the PTO during the prosecution of the *'565 patent* is not sufficient to prove inequitable conduct. Rather, clear and convincing evidence must also establish an intent to deceive the PTO. To prove intent, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Digital Control Inc.*, 437 F.3d at 1319 (quoting *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189 (Fed.Cir.1993)). Direct evidence of intent to deceive is not necessary, but may be inferred from the surrounding circumstances. *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1256 (Fed.Cir.1997). We have held that absent a credible reason for withholding the information, "[i]ntent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application."

(Cont'd)

Gene reference by expressly arguing that it "fails to describe the development of a chimearic gene." It can, thus, not now argue that the Mariani notes, which do disclose a chimeric gene, are merely cumulative over the Adang *Gene* article. Moreover, unlike the Mariani notes, nothing in the Adang reference could refute Bayer's interpretation of the Barnes Abstract. A reference cannot be merely cumulative if there is no other reference which "refutes, or is inconsistent with" a position the applicant has taken in opposing an argument of unpatentability.

Id.; *see also Bruno Indep. Living Aids*, 394 F.3d at 1354 (holding that an "inference of deceptive intent may fairly be drawn in the absence" of a "credible explanation for the non-disclosure"); *cf. Dayco Prods.*, 329 F.3d at 1367 ("Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.").

The district court did not clearly err in finding that Bayer's "attempts to establish subjective good faith sufficient to overcome the intent to mislead [were] not persuasive" and concluding that Meulemanns intentionally withheld the material Mariani notes with the intent to deceive the PTO. *Monsanto II*, slip op. at 97-98. Meulemanns himself admitted that he was aware of the notes during the prosecution of the '565 patent, that he had discussed the content of the notes with Mariani, and that the notes would have been important to the Examiner if the notes contained reliable information. The only explanation that Meulemanns or Bayer provided for failing to disclose the information contained in the notes was that the notes were not decipherable standing alone and that when Meulemanns discussed the notes with Mariani, Mariani had been unable to remember "anything" about them. The district court, however, found this explanation to lack credibility, particularly in light of Mariani's ability to testify with clarity and detail about the contents of the notes during her deposition. We find nothing clearly erroneous in the court's credibility finding. *See First Interstate Bank of Billings v. United States*, 61 F.3d 876, 882 (Fed.Cir.1995) ("[C]redibility determinations by the trial judge 'can

virtually never be clear error.' " (quoting *Anderson v. City of Bessemer*, 470 U.S. 564, 575, 105 S.Ct. 1504, 84 L.Ed.2d 518 (1985))); *JVW Enters. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1334 (Fed.Cir.2005). And absent a credible reason for Meulemanns to have not understood the content of Mariani's notes after having discussed them with Mariani, the district court did not clearly err in inferring the requisite intent. *See Bruno Indep. Living Aids*, 394 F.3d at 1354. Intent is easily inferred when, as here, an applicant makes arguments to the PTO that it knows, or obviously should have known, are false in light of information not before the examiner, and the applicant knowingly withholds that additional information. *See Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1368 (Fed.Cir.2007) (holding that an applicant's argument that the information was withheld in " 'good faith' does not negate an intent to manipulate the evidence" when "an applicant knows or obviously should know that information would be material to the examiner").

Having found without clear error that Bayer intentionally withheld material information when it failed to disclose the Mariani notes despite taking a position at the PTO that was refuted by the information contained in the notes, the district court had discretion to hold the *'565 patent* unenforceable for inequitable conduct. *See Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed.Cir.2003). As Bayer does not challenge this discretionary decision, we affirm the district court's holding that the *'565 patent* is unenforceable for inequitable conduct.

Appendix B

Because the failure to disclose the information in the Mariani notes was alone sufficient to support holding the *'565 patent* unenforceable, we need not consider whether the statement Bayer made during the prosecution of the patent that its invention had solved the problem of unpredictability of expression of Bt toxins in plants also amounted to inequitable conduct.

III.

The district court also concluded that the '799, '372 and *'546 patents* were unenforceable for inequitable conduct. Bayer argues on appeal that the district court did not have jurisdiction to hold these three patents unenforceable. We review questions of jurisdiction *de novo. See, e.g., Pennington Seed, Inc. v. Produce Exch. No. 299,* 457 F.3d 1334, 1338 (Fed.Cir.2006).

Although Monsanto initially sought a declaratory judgment that four Bayer patents were infringed, Bayer subsequently dismissed with prejudice its infringement claims under the '799, '372, and *'546 patents* and filed a Statement of Non-Liability, covenanting not to sue Monsanto for past, present, or future infringement of these patents. Even if filing such a covenant may divest the court of jurisdiction over a declaratory judgment action regarding these patents, *see Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed.Cir.1999); *Fort James Corp. v. Solo Cup Corp.*, 412 F.3d 1340 (Fed.Cir.2005), under our precedent the district court retained independent jurisdiction over

Monsanto's request for attorney fees under 35 U.S.C. § 285. As this court recently explained:

> While the covenant [not to sue for infringement] may have eliminated the case or controversy pled in the patent-related counterclaims and deprived the district court of Article III jurisdiction with respect to those counterclaims, the covenant does not deprive the district court of jurisdiction to determine the disposition of . . . the request for attorney fees under 35 U.S.C. § 285.

Highway Equip. Co. v. FECO, Ltd., 469 F.3d 1027, 1033 n. 1 (Fed.Cir.2006) (internal citation omitted); *see also H.R. Techs., Inc. v. Astechnologies, Inc.*, 275 F.3d 1378, 1385 (Fed.Cir.2002).

The parties do not dispute that the district court's jurisdiction to rule on attorney fees encompassed the jurisdiction to make findings of inequitable conduct regarding all four patents. *See Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed.Cir.2001) ("A district court may award reasonable attorney fees to the prevailing party in a patent infringement case where the conduct of a party is deemed to be 'exceptional.'. . . . The prevailing party may prove the existence of an exceptional case by showing: inequitable conduct before the PTO . . . ." (quoting 35 U.S.C.

§ 285)).[17] The district court's holding that the '799, '372, and *'546 patents* are unenforceable stemmed directly from its inequitable conduct findings. *See Monsanto II*, slip op. at 95 ("The Court . . . finds by clear and convincing evidence that the equities warrant a conclusion that . . . Bayer committed inequitable conduct. . . . The '799 patent, the '372 patent, and the '546 patent are accordingly unenforceable."). The question facing this court is, thus, whether a district court's jurisdiction under § 285 to determine whether there was inequitable conduct in the prosecution of patents that are otherwise no longer in suit confers on that court the jurisdiction to hold such patents unenforceable for inequitable conduct. We hold that it does.

A district court has no discretion to decide whether a patent is unenforceable once it enters a finding of inequitable conduct. To the contrary, this court has long held that the unenforceability of a patent follows automatically once a patent is found to have been obtained via inequitable conduct. *Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed.Cir.1988) (en banc in pertinent part) ("When a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent *is* rendered unenforceable." (emphasis added)); *see also*

17. Inequitable conduct regarding the three withdrawn patents was relevant to the question of attorney's fees because Monsanto's request for attorney's fees included fees accumulated before the three patents had been withdrawn.

Appendix B

J.P. Stevens & Co. v. Lex Tex, Ltd., 747 F.2d 1553, 1560 (Fed.Cir.1984) ("If the court reaches th[e] conclusion [that there was inequitable conduct], it must hold that the patent claims at issue are unenforceable."). Any distinction between the two findings is merely semantic. As a result, jurisdiction to decide whether a patent was obtained through inequitable conduct necessarily includes the jurisdiction to declare a patent unenforceable as a result of that inequitable conduct.

In an opinion issued after the briefs were filed in the instant case but prior to oral argument, this court explicitly held that a district court has the power to declare patents that are no longer in suit unenforceable for inequitable conduct. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223 (Fed.Cir.2007). In *Nilssen*, the plaintiff had originally alleged that the defendant infringed fifteen patents related to electrical lighting products but withdrew four of the patents shortly before trial. The district court nevertheless held the four withdrawn patents unenforceable for inequitable conduct in the process of determining whether the patents which remained in the suit were unenforceable for inequitable conduct. This court affirmed, explaining that "[b]ecause inequitable conduct with respect to one or more patents in a family can infect related applications, we find no abuse of discretion in the district court's holding the [four patents no longer in suit] unenforceable." *Id.* at 1230. In *Nilssen* the jurisdiction of the court to reach the inequitable conduct inquiry for the withdrawn patents was itself in question because the district court reached the issue only collaterally to

determining whether there was inequitable conduct regarding patents that remained in suit. Here, the outcome is even clearer as there is no dispute that the court had an independent grant of jurisdiction under § 285 to consider inequitable conduct relating to the withdrawn patents. The district court, therefore, did not lack jurisdiction to hold the '799, '372, and *'546 patents* unenforceable.[18]

IV.

We affirm the district court's holding that the '565 patent is unenforceable for inequitable conduct, and we conclude that the court did have jurisdiction to declare the '799, '372, and *'546 patents* unenforceable. Since we affirm the court's holding that the *'565 patent* is unenforceable, we do not reach the remaining issues raised by Bayer on appeal. The final judgment of the district court is therefore

AFFIRMED.

Costs to appellee.

---

18. Bayer does not, in this appeal, challenge the district court's findings of inequitable conduct regarding the '799, '372, and *'546 patents*. Therefore, those findings are affirmed. We do not address the impact of those findings on the question of attorney fees under section 285.

APPENDIX C — JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION DATED APRIL 12, 2007

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Case No. 4:00CV01915-ERW

MONSANTO COMPANY,

Plaintiff(s),

vs.

BAYER CROPSCIENCE, N.V.,

Defendant(s).

JUDGMENT

In accordance with the Memorandum and Order entered on this date and incorporated herein,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that Defendant Bayer BioScience N.V. shall pay $8,514,062.10 to Plaintiff Monsanto Company in costs and attorney's fees.

Dated this 12th Day of April, 2007.

s/ E. Richard Webber
E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE

APPENDIX D — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION DATED APRIL 12, 2007

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Case No. 4:00CV01915-ERW

MONSANTO COMPANY,

Plaintiff(s),

vs.

BAYER CROPSCIENCE, N.V.,

Defendant(s).

MEMORANDUM AND ORDER

This matter comes before the Court on Plaintiff Monsanto Company's ("Plaintiff" or "Monsanto") Motion for Determination of Exceptional Case under 35 U.S.C. § 285 and Award of Attorneys' Fees [doc. #898], and for an award of costs [doc. #895].

I. PROCEDURAL HISTORY

Monsanto filed suit against Bayer Cropscience, N.V. ("Bayer" or "Defendant") seeking a declaration from this Court that its Mon810 YieldGard® corn ("Mon810 Corn") products do not infringe the claims of four United

States patents owned by Bayer. Bayer then filed a counterclaim against Monsanto for patent infringement. This Court initially granted Summary Judgment in favor of Monsanto, on the basis that the patents in question were unenforceable due to Bayer's inequitable conduct before the Patent and Trademark Office ("PTO"). The Court also found that the collateral estoppel effect of a prior decision on a similar patent required this Court to hold that all of the asserted claims of the '546 patent and two of the claims of the '372 patent were invalid and that Monsanto did not infringe any of the asserted claims of the '799 patent. Lastly, the Court held that Monsanto was entitled to summary judgment of non-infringement as to all of the asserted claims of the '565 patent and one of the asserted claims of the '372 patent based on the construction of the claim term Bt2 toxin. These holdings were overruled by the Federal Circuit. *Monsanto Co. v. Bayer Bioscience N.V.*, 363 F.3d 1235 (Fed.Cir.2004). Specifically, the Federal Circuit held that there was a material issue of fact regarding whether there was inequitable conduct by Bayer during the prosecution of its patent application, based on an affidavit, submitted to this Court by Mr. Jansens, explaining the declaration submitted to the PTO which was the basis of this Court's finding of inequitable conduct. The Federal Circuit further held that although the questions in this case were similar to the earlier case of *Plant Genetic Systems N.V. v. Dekalb Gentics Corp.*, 175 F.Supp.2d 246 (D.Conn.2001)[1], they were not

1. This was the case this Court relied on in finding that Defendant Bayer was collaterally estopped from raising certain arguments before this Court.

identical and therefore collateral estoppel was inappropriate; collateral estoppel effect would be appropriate only if Monsanto was successful in showing by clear and convincing evidence that the specifications of the '546 and '372 patents do not teach one of ordinary skill how to transform a monocot with a gene for a Bt toxin, which Monsanto had not done prior to Summary Judgment. Lastly, the Federal Circuit held that this Court's claim construction of the term "Bt2 toxin" was incorrect, because the Court based its construction on the source of the toxin, rather than the amino acid sequence of the toxin. For the above cited reasons the Federal Circuit reversed this Court's summary judgment order and remanded the case to this Court for further proceedings.

On remand, Bayer dismissed its counterclaims of infringement of the '799, '372, and '546 patents, leaving only infringement of the '565 patent to be tried on remand. However, Monsanto's original action for declaratory judgment regarding validity remained as to all patents. Subsequently, Bayer sought and received summary judgment from this Court that the circumstances of the Jansens' declaration could not impact the '565 patent based on infectious unenforceability. A jury returned a verdict on November 22, 2005, finding that Monsanto's Mon810 Corn did not infringe the Bayer patent, that the claims of the '565 patent were invalid because of prior inventorship, and the '565 patent was invalid for obviousness in view of prior art. This Court then held an inequitable conduct hearing on February 21, 2006 which continued through

February 24, 2006. The Court found that all four patents were invalid due to inequitable conduct. There was a great deal of testimony provided to the Court, which is thoroughly articulated in this Court's prior order, that supports this Court's finding of inequitable conduct. Bayer failed to provide the PTO with test results that were negative for any insecticidal activity, in a number of different plants. *See* Docket No. 894 at p. 6. Specifically, Mr Jansens, who submitted a declaration which was filed with the PTO, knew of the negative test results, evidenced by a meeting he attended where the negative results were reported. *Id.* This Court further held that the information withheld was material. Following this Court's ruling of inequitable conduct by Bayer, Plaintiff Monsanto filed the pending motions for costs and for attorneys' fees.

II. FACTUAL BACKGROUND

Monsanto filed suit against Bayer seeking a declaration from this Court that their Mon810 Corn did not infringe any of Bayer's patents. Monsanto based its suit on the argument that the patents were invalid due to Bayer's inequitable conduct. The four patents involved in this litigation are U.S. Patents No. 5,545,565 ("the '565 patent"), No. 6,767,372 ("the '372 patent"), No. 6,107,546 ("the '546 patent"), and No. 5,254,799 ("the '799 patent"). All four patents were based on an invention that took advantage of a known system for introducing foreign DNA into a plant cell's genome by using the bacterium Agrobacterium tumefaciens ("Agrobacterium"), which has the ability to transform the genome of certain

plants. The Agrobacterium is then transformed so that its genome contains a chimeric gene comprising a DNA fragment that encodes a truncated form of the Bt insecticidal protein. The purpose of this process is to develop plants, especially crops, which contain insecticidal levels of the Bt toxin, so that they will be resistant to insecticides. Monsanto developed, and sells, genetically altered corn seeds that produce corn which expresses a Bt toxin at insecticidal levels. The present suit was initiated by Monsanto. Bayer then counter-claimed against Monsanto for infringement.

III. BILL OF COSTS[2]

Monsanto has filed a motion for costs, in accordance with Federal Rule of Civil Procedure 54(d). Rule 54(d) provides that "[e]xcept when express provision therefore is made either in a statute of the United States or in these rules, costs other than attorney's fees shall be allowed as of course to the prevailing party unless the court otherwise directs. . . ." Fed.R.Civ.P. 54(d). 28 U.S.C § 1920 provides what items may be taxed as costs:

(1) Fees of the clerk and marshal;

---

2. The Court notes that certain costs were included by Plaintiff in both its request for Bill of Costs, and in its Motion for Attorney's Fees and Expenses under 35 U.S.C. § 285. Plaintiff clearly points out that it is not seeking a double recovery, but rather that such costs could be awarded under either statute. Any award that this Court makes under 28 U.S.C. § 1920 that are also requested under 35 U.S.C. § 285, will be subtracted where appropriate.

(2) Fees of the court reporter for all or any party of the stenographic transcript necessarily obtained for use in the case;

(3) Fees and disbursements for printing and witnesses;

(4) Fees for exemplification and copies of papers necessarily obtained for use in the case;

(5) Docket fees under section 1923 of this title;

(6) Compensation of court appointed experts, compensation of interpreters, and salaries, fees, expenses, and costs of special interpretation services under section 1828 of this title.

28 U.S.C. § 1920. Following this Court's Summary Judgment ruling, prior to the Federal Circuit remanding the case, this Court entered an award of costs in favor of Plaintiffs in the amount of $108,954.32. The Court allowed all requested costs with the exception of $27,428.28 for "luxury items" related to court reporting costs. Following appeal, and subsequent success at trial on remand, the Plaintiffs now seek an award of $138,880.46 for costs. Plaintiffs note that the request for costs was adjusted in accordance with this Court's prior order, reducing it for the luxury items noted above,

with the exception of videotaping costs.[3] The only additional costs asserted by Plaintiffs is for original trial transcripts, however, they have omitted any costs for Realtime or ASCII costs which were previously disallowed by this Court.

The only objection Bayer asserts to Plaintiffs' Bill of Costs is to those costs associated with videotape depositions. In this Court's prior ruling the Court held that although most court's have allowed the recovery of costs associated with videotape depositions, such a recovery was not appropriate in this case because Plaintiffs failed to articulate why videotapes and transcripts were "necessarily obtained for use in the case." Docket No. 413, November 14, 2003, p. 8 (citing 28 U.S.C. § 1920). In Plaintiffs' current motion for costs, they repeat this request and articulate that such videotapes were necessary to aid both the jury and the Court in independently assessing the demeanor and credibility of each witness.

As the only disputed issue is over the cost of videotape depositions, this will be the focus of the Court's discussion. As was stated by this Court in its previous order, "section 1920(2) implicitly permits taxation of the costs of video depositions." *Cherry v. Champion International Corp.*, 186 F.3d 442, 448 (4th Cir.1999); *see also Tilton v. Capital Cities/ABC, Inc.*,

---

3. *Pl. Memo in Support of Pl. Mot. For Bill of Costs*, 1 ("Monsanto has removed all costs associated with rough transcripts, Realtime costs, ASCII deposition costs, condensed transcripts, and delivery and shipping charges.").

115 F.3d 1471, 1477 (10th Cir.1997); *Morrison v. Reichold Chemicals, Inc.*, 97 F.3d 460, 464-65 (11th Cir.1996). The Circuit Court opinions cited have reasoned that although 28 U.S.C. § 1920 doesn't explicitly provide for costs from videotape depositions, they are implicitly permitted when this statute is read in conjunction with Federal Rule of Civil Procedure 30(b)(2)-(3). *Tilton*, 115 F.3d at 1477 ("Interpreting section 1920(2) in conjunction with Rule 30(b)(2)-(3) implicitly permits taxation of the costs of video depositions."). Rule 30(b)(2) provides that "[t]he party taking the deposition shall state in the notice the method by which the testimony shall be recorded. Unless the court orders otherwise, it may be recorded by sound, sound-and-visual, or stenographic means. . . ." The Court ruled "that although the costs of video depositions may be recoverable, a prevailing party is not necessarily entitled to recover the costs of both transcribing and videotaping the deposition." Docket No. 413, November 14, 2003, p. 8.

The Court concluded in its November 14, 2003 order that the Plaintiff, as the prevailing party, had not made an adequate showing of necessity to recover costs for both. However, the Court does not believe the same result necessarily follows today. One of the basis for this Court's previous order was the Plaintiff's failure to make a showing of why the video depositions were required. Docket No. 413, November 14, 2003, p. 8. The Tenth Circuit discussed the wisdom of allowing such recovery; "Videotaped depositions are a necessary and time effective method of preserving witnesses' time and

BEST AVAILABLE COPY

allocating precious court and judicial time in this age of advanced court technology and over-crowded court calenders." *Tilton*, 115 F.3d at 1477 (internal citation omitted). The court held in that case that "the district court did not abuse its discretion in taxing the costs of both the preparation and transcription of the seven videotaped depositions." *Id.* at 1478. Plaintiff has provided sufficient reason for requiring the videotaping of the depositions as well as their transcription, and therefore the costs will be charged to Defendant. Specifically, now there is a sufficient showing that it was beneficial to this Court in making its determinations of credibility of both Plaintiff and Defendant witnesses to have a videotape representation. As was evident from the opinion entered in this case, the question of credibility played a large role in this case, and therefore the Court concludes such costs are reasonably recoverable.

IV. ATTORNEY'S FEES AND EXCEPTIONAL CASE DETERMINATION

A. LEGAL STANDARD

United States Patent law provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. In making this decision the Court will look at Federal Circuit case law, as this is an issue unique to patent law. *Special Devices, Inc. v. OEA, Inc.*, 269 F.3d 1340, 1343 (Fed.Cir.2001) ("[T]he awarding of attorney fees pursuant to 35 U.S.C. § 285 is an issue unique to patent law and therefore

subject to Federal Circuit law."). As is true under any fee-shifting statute, such statute is to be construed narrowly, as it is contrary to the American Rule that parties should pay their own litigation expenses, including attorney's fees. *Machinery Corp. of America v. Gullfiber AB*, 774 F.2d 467, 471 (Fed.Cir.1985) ("Under the 'American Rule,' the prevailing litigant is ordinarily not entitled to any attorney fees, absent statutory authority."). Furthermore, "it is not contemplated that the recovery of attorney's fees will become an ordinary thing in patent suits. . . ." *Id.* at 472.

In order for a district court to award attorney's fees, the court must undertake a two-step inquiry. *Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1315 (Fed.Cir.2005). "The court examines first whether there is clear and convincing evidence that the case is exceptional, and second whether an award of attorney fees to the prevailing party is warranted." *Id.* As cited by this Court in its order finding inequitable conduct by Bayer, "inventors, patent owners, and attorneys associated with the filing or prosecution of a patent application have an affirmative and continuing duty to disclose material information to the PTO." *Id.* Specifically, the Federal Circuit stated that "[t]he prevailing party must prove the existence of an exceptional case by showing: inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified and otherwise bad faith litigation; a frivolous suit or willful infringement." *Brasseler, U.S.A., L.P. v. Stryker Sales Corp.*, 296 F.3d 1370, 1380 (Fed.Cir.2001). The *Bresseler* court further stated that "exceptional cases

are normally those involving bad faith litigation or those involving inequitable conduct by the patentee in procuring the patent." *Id; see also Cambridge Products Ltd. v. Penn Nutrients Inc.*, 962 F.2d 1048, 1050-51 (Fed.Cir.1992) ("In the case of awards to prevailing accused infringers . . . , 'exceptional cases' are normally those of bad faith litigation or those involving fraud or inequitable conduct by the patentee in procuring the patent.").

The Federal Circuit requires that the district court find by clear and convincing evidence that a case is exceptional. *Id.* at 1378-79 ("Direct or circumstantial evidence that is clear and convincing is needed to establish an exceptional case." (internal quotation omitted)). Furthermore, even if the district court makes a determination that the case is exceptional, it is within the discretion of the court to award attorney's fees. *Consolidated Aluminum Corp. v. Foseco International Ltd.*, 910 F.2d 804, 815 (Fed.Cir.1990). Specifically the Federal Circuit stated that "not every case deemed exceptional must result in a fee award." *Id.* "The requirement in Section 285 of establishing an 'exceptional case' remains a formidable and adequate barrier to unwarranted awards." *Mathis v. Spears*, 857 F.2d 749, 754 (Fed.Cir.1988).

B. DISCUSSION

Plaintiffs assert two of the bases articulated by the *Brasseler* court in support of their assertion that this is an exceptional case. 267 F.3d at 1380. First, Plaintiffs

argue that the finding of inequitable conduct based on the false declaration by Mr. Jansens in regard to the '799, '372, and '546 patents, and Dr. Meulemans's false testimony regarding the '565 patent, are sufficient to support this Court's finding of an exceptional case. Secondly, Monsanto argues that Bayer's counter-claims regarding the three patent claims that were ultimately dropped, '799, '372, and '546, were based upon a theory that Bayer knew to be factually baseless, thus constituting bad faith litigation. For the following reasons, this Court agrees with Plaintiffs' first argument, that this is an exceptional case, and that an award of attorneys' fees is appropriate; it is therefore unnecessary to address the bad faith argument.

1. Exceptional Case

Although Defendants correctly assert that this Court is not required to make a finding of an exceptional case based solely on the fact that this Court found inequitable conduct, the level of inequitable conduct that was found by this Court is clearly sufficient to support such a finding. This Court stated that

> [t]he orchestration of deceit, of purposeful misrepresentation of material fact, of intentional non-disclosure of material information, and submission of false material information, with intent to deceive and mislead the United States Patent Office Examiner has been proved by clear and convincing evidence. The weighing of equities

> of the parties clearly and convincingly warrants a conclusion that Bayer and its antecedent companies committed inequitable conduct. . . .

Docket No. 894, p. 91. Contrary to Defendants assertion that the determination of inequitable conduct was a close one, this case shows an extreme company policy of doing whatever was necessary to get the broadest, and most lucrative, patent protection. The award of attorney's fees under 35 U.S.C. § 284 is intended as a deterrent to "the improper bringing of clearly unwarranted suits on obviously invalid or unenforceable patents. . . ." *Mathis*, 857 F.2d at 754.

Furthermore, those cases cited by Defendants in support of their argument that this was a close case, address the bad faith conduct of a party in patent litigation, which is distinguishable from the case at bar. *See e.g. Phonometrics, Inc. v. Choice Hotels International, Inc.*, 186 F.Supp.2d 1231, 1232 (S.D.Fl. 2002) ("When a party makes a colorable, albeit weak, argument that was not raised in bad faith, the court should not grant attorneys [sic] fees. . . . Conversely, when a claim is clearly hopeless and unquestionably without any possible basis in fact or law, the court has discretion to award attorneys' fees." (Internal quotation omitted)). The basis for this Court's exceptional case finding is the Defendant's inequitable conduct before the PTO, not its bad faith in litigating before this Court. This is supported by the language in this Court's August 8, 2006 order, which stated:

Appendix D

> In any ruling or reference made herein, it must be clearly understood, that attorneys for both parties, who have borne substantial burdens in complying with the Court's orders, have made an enduring impression by always observing the highest tenets of professionalism, and they have displayed mutual respect for their worthy adversaries and for the Court. Any findings of inequitable conduct or actionable conduct of any kind is ascribed to no lawyers in the jury trial or in this equitable proceeding. All have recognized the bounds of effective advocacy and have practiced their very substantial skills in representing their clients in the most appropriate manner.

Docket No. 894, p. 89. Defendants point to this statement in support of their argument that a ruling that this is an exceptional case warranting an award of attorney's fees is inappropriate. While it is true that an exceptional case finding can be based on the bad faith actions of attorneys, *See Evident Corp.*, 399 F.3d at 1315, it is not an essential element. The simple fact that the attorneys in this case acted with respect towards each other and the Court, is not sufficient to prevent an award of attorney's fees. The Federal Circuit, in *Evident Corp.*, also stated that an exceptional case finding may be based on the actions of the patent holder, which is what took place in the case at bar. *Id.* This Court finds that the actions by Bayer, and its employees, were done with a disregard for the truth, and therefore warrant a finding of an exceptional case.

2. Attorneys' Fees and Expenses

Once a determination of an exceptional case has been found, the second part of the inquiry is whether this Court will exercise its discretion in awarding attorney's fees and costs. "After the district court determines the case is exceptional, there remains in every case its freedom to exercise its discretion 'informed by the court's familiarity with the matter in litigation and the interest of justice' " to award attorney's fees. *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1215 (Fed.Cir.1987) (quoting *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F .2d 198, 201 (Fed.Cir. 1986)); *see also Perricone v. Medics pharmaceutical Corp.*, 432 F.3d 1368, 1380-81 (Fed.Cir.2005). In accordance with the determination made by this Court after it's first summary judgment ruling, before remand, this Court finds that an award of attorney's fees is appropriate. Plaintiffs have spent a large amount of time and money in defending against the counterclaims asserted by Bayer and in prosecuting their action for a declaratory judgment, all of which was necessitated by the bad faith of Defendants in seeking a patent that was overly broad, and which was granted due to misinformation provided to the PTO. The exceptional circumstances requirement strikes a balance between the interest of the patentee in protecting his statutory rights and the interest of the public in confining such rights to their legal limits." *National Diamond Syndicate, Inc. v. Flanders Diamond U.S.A., Inc.*, 2003 WL 21663673, *6 (N.D. Ill. July, 15 2003); *see also eSpeed, Inc. v. Brokertec U.S.A., L.L.C.*, 417 F.Supp.2d

580, 600 (D.Del.2006) ("To determine whether attorneys' fees are warranted, a trial judge should weigh considerations such as the closeness of the case, the tactics of counsel, the conduct of the parties, and any other factors that may contribute to a fair allocation of the burdens of litigation as between winner and loser." (Internal citation omitted)). The balance in this case clearly warrants an award of attorneys' fees in favor of Plaintiffs. Although Defendants are correct that the Federal Circuit remanded this Court's summary judgment ruling on the question of inequitable conduct, this alone does not provide a basis for Defendants argument that this was a close case. Defendants' responsive brief is an attempt to reargue the question of inequitable conduct, however, this was conclusively decided by the Court in its earlier opinion. Defendants further argument regarding bad faith litigation are inapplicable, as stated by the Court earlier, the determination that this is an exceptional case is based not on Bayer's bad faith in litigating the present action, but on its bad faith before the PTO.

In its prior ruling, this Court authorized an award of $4,616,202.00[4] for attorneys' fees, and $72,827.89 in additional costs and expenses. Monsanto now seeks $9,060,923.99 in attorneys' fees and costs. Defendants

---

4. This was split between the Howrey, White law firm ($4,313,437.00) and Husch & Eppenberger, L.L.C. ($302,764.50). The Court notes a difference of $.50, however, due to the immaterial nature of the discrepancy, the total attorney fee awarded before appeal and remand is approved as it was in the prior ruling.

raise a number of arguments disputing this amount. First, Defendants argue that there are mathematical errors in Monsanto's calculation of fees. Secondly, Defendants argue that the lodestar analysis mandates a different result, as the number of hours, and the hourly rate are both unreasonable. Thirdly, Defendants argue that an award of attorneys' fees should only be permitted for those costs associated with the conduct found to be inequitable, not for all of Monsanto's fees. Fourthly, Defendants assert that Plaintiffs expenses are unreasonable, and are not limited to those permitted by this Court in its prior exceptional case ruling. Fifthly, Defendants argue that certain items are included as 35 U.S.C. § 285 expenses as well as under the Bill of Costs, and should be limited to one or the other. Lastly, Defendants argue that 35 U.S.C. § 285 does not authorize reimbursement of expert witness fees. The Court will address each of Defendants arguments in turn, and will carefully review all of the expenses and fees Monsanto seeks to have paid by the Defendants.[5]

a. Attorneys' Fees

The first argument is that their was a mathematical error in Monsanto's calculation of attorney's fees. Specifically, that the records provided by Monsanto

---

5. Monsanto argues, in its reply memorandum, that the declaration of Mr. Gary Greenfield (the Greenfield Declaration), submitted by Defendants, is inadmissible as it fails to meet the requirements of Federal Rule of Evidence 702. This Court will look at the Greenfield Declaration, along with all other relevant evidence in reaching a determination of the appropriate attorney fee award.

show only $8,308,348.00 not $8,545,677.50 that Monsanto claims. Monsanto responded by stating that a billing receipt had been omitted which accounted for the difference, but that Monsanto would not be opposed to a reduction for failing to supply sufficient documentation. Accordingly, the Court will use the starting amount of $8,308,348.00, for attorneys' fees.

The second argument addresses the lodestar amount. The Supreme Court has held that "[t]he most useful starting point for determining the amount of a reasonable fee is the number of hours reasonably expended on the litigation multiplied by a reasonable hourly rate." *Hensley v. Eckerhart*, 461 U.S. 424, 434 (1983). The Supreme Court also stated that "[c]ounsel for the prevailing party should make a good faith effort to exclude from a fee request hours that are excessive, redundant, or otherwise unnecessary, just as a lawyer in private practice ethically is obligated to exclude such hours from his fee submission. . . . Hours that are not properly billed to one's *client* also are not properly billed to one's *adversary* pursuant to statutory authority." *Id.* at 434 (internal citation omitted) (emphasis in original). The Fifth Circuit in *Johnson v. Georgia Highway Express, Inc.*, listed twelve factors which are commonly cited for determining a reasonably attorney fee award. 488 F.2d 714 (5th Cir.1974).[6] However, as noted by the

6. The factors enumerated by the Fifth Circuit are: 1) the time and labor required, 2) the novelty and difficulty of the questions, 3) the skill requisite to perform the legal service properly, 4) the preclusion of other employment by the attorney (Cont'd)

Supreme Court in *Hensley*, "many of these factors usually are subsumed within the initial calculation of hours reasonably expended at a reasonable hourly rate. 461 U.S. at 434 n. 9.

Both parties rely upon the American Intellectual Property Law Association's (AIPLA) survey, which reports the average hourly rates, and total billing amounts for a variety of patent law cases, in a variety of regions. Plaintiffs assert that the average cost for litigating a patent infringement cases, where over $25 million in damages are sought, is $5,175,753.00 with mean amounts varying between $3.2 million and $9.4 million depending on region. Plaintiff further asserts that due to the complexity of the case, the requirement of not only a jury trial but also a four day inequitable conduct hearing, and the significant amount of damages at stake, the higher end of these averages is appropriate. Defendants more specifically look to the mean hourly rate billed and the mean litigation expenses specifically for the Midwest region of the country and argue the amount should be lower. The Court has reviewed the AIPLA guidelines, which are helpful in determining a reasonable fee, and notes that Plaintiffs'

(Cont'd)

due to acceptance of the case, 5) the customary fee, 6) whether the fee is fixed or contingent, 7) time limitations imposed by the client or the circumstances, 8) the amount involved and the results obtained, 9) the experience, reputation, and ability of the attorneys, 10) the undesirability of the case, 11) the nature and length of the professional relationship with the client, and 12) awards in similar cases. *Johnson*, 488 F.2d at 717-719.

requested fees are within the averages cited for a case of this type, although it is high for a case in the Midwest. However, the Court is not inclined to reduce the requested amount based solely on the averages quoted in that report. Each case has its own set of facts and its own intricacies; as Plaintiffs correctly point out this case was particularly complicated. The amount sought by the Plaintiffs is not beyond the realm of acceptable according to AIPLA.

Although the requested fees are within the guidelines cited, Defendants raise a number of legitimate questions regarding the billing records. The Court will look at each assertion and adjust the total fee award accordingly.[7] The first issue is the costs incurred between this Court's original order in this case, and the second trial[8] that was held. Defendants assert that the $2,204,271.53 in attorneys' fees billed between the time the case was remanded, and the time of the second trial, were unnecessary, because Plaintiffs already billed for these expenses prior to the summary judgment being granted. Plaintiffs respond that it is unreasonable to argue that no work should have been conducted between this Court's December 28, 2002

---

7. For ease in analyzing the information, the Court will go through the "Summary of Analysis" included in the Greenfield Declaration, and where other information is drawn upon, the Court will note accordingly.

8. The Court notes that there was no first trial in this case. However, the term is used to distinguish from billing that was submitted in preparation for the first trial, before Summary Judgment was entered.

entry of Summary Judgment, and jury selection which began on October 31, 2005. Monsanto gives a detailed list of all the expenses incurred during that period. This Court believes all those expenses are reasonable, with the exception of the $63,055.65 incurred for the ultimately unsuccessful infectious unenforceability argument relating to the '565 patent. These fees are not reasonably placed on the Defendant, the remainder of the $2,204,271.53 is recoverable.

Defendants next seek to reduce the attorneys' fee award by $609,750.92 for problems with billing practices, and by $986,125.11 for reduction in the hourly rates used. Having reviewed the declarations by attorneys for both Husch & Eppenburger, L.L.C., and Howery L.L.P., this Court does not believe that either law firm was in the practice of over billing its clients.[9] Furthermore, this was an extremely complex case, which undoubtedly took a great deal of attorneys a great deal of time in preparing to go to trial. Therefore the reductions in rates and time billed sought by the Defendants will not be made.

The last significant dispute raised by Defendants regarding the fees billed, is for those entries that are partially redacted. No request for fees was made for those entries that were completely redacted, but a request for fees was made for entries that were only partially redacted. Having reviewed the partially

9. All fees were billed to the client, which the Supreme Court noted in *Hensley*, is a factor in whether such fees are reasonably billed to the opposing party. 461 U.S. at 434.

redacted entries, they are not so vague as to prevent this Court from reviewing the reasonableness of the hours billed. Although some detail has been removed, the activities listed do not appear unreasonable, and the recovery of these fees will be permitted.

Bayer's third argument asserts that any attorneys' fees awarded should be limited to those relating to the inequitable conduct finding. The Supreme Court in *Hensley*, stated that "work on an unsuccessful claim cannot be deemed to have been expended in pursuit of the ultimate result achieved." 461 U.S. at 435 (internal citation omitted). Defendants' arguments on this issue are unpersuasive. "Where a plaintiff has obtained excellent results, his attorney should recover a fully compensatory fee." *Id.* It is clear in the case at bar that although this Court mistakenly ruled in favor of Plaintiffs on Summary Judgment, this does not change the ultimate success of the Plaintiffs at trial and in the inequitable conduct hearing. Furthermore, Plaintiffs were obligated to defend those claims asserted by the Defendants, even those that were eventually dropped from the action. Defendants cite to *Beckman Instruments, Inc. v. LKB Produkter AB*, however, that case is not helpful to the Defendants position. 892 F.2d 1547 (Fed.Cir.1989). The court found that the district court was incorrect in awarding all attorney's fees, as not all expenses incurred by the prevailing party were a result of the vexatious litigation strategy. *Id.* at 1553. However, the court further stated that "this case differs from cases in which willful infringement on the part of an infringer or inequitable conduct on the part of a

patentee *led* to the bringing of the lawsuit." *Id.* (emphasis in original). That is the exact situation that is present in the case at bar. The inequitable conduct of Defendants, led the PTO to issue a patent that was overly broad, and which then required a lawsuit by Monsanto to prevent an action for infringement, and the potential for serious economic harm resulting from the loss of sales of its Mon810 Corn. Monsanto's results in this action were excellent, as all patents were invalidated and the jury returned a verdict of non-infringement, therefore Monsanto is entitled to be fully compensated. *Hensley*, 461 U.S. at 435. The Court is not inclined to divide the fee based on whether hours were spent in preparation for one legal question or another, rather the entire case surrounded a determination of the validity of Defendants' patents, and such patents were ultimately found to be unenforceable.

Accordingly, this Court concludes that Monsanto should be permitted to recover attorneys' fees in the amount of $8,245,292.35. Although this is a large attorneys' fee award, there is no doubt that the years of litigation which were required in such a complex case, as a result of the inequitable conduct of Bayer, justify such an award.

b. Expenses

Defendants' fourth, fifth and sixth arguments relate to the inclusion of expenses in an award under 35 U.S.C. § 285. Although certain additional expenses are recoverable under this provision, this Court limited

those recoveries in its prior order to $72,827.89, specifically those expenses for research and postage. Defendants assert that any additional amount recoverable should also be limited to those expenses for postage and research costs, or $57,061.32. Plaintiffs assert that the total post appeal expenses total $431,290.30. The Court agrees with the Defendant that those expenses allowed should be limited, as they were in this Court's prior order. Furthermore, as this Court permitted the recovery of all costs above, those costs also requested under 35 U.S.C. § 285, will be deducted. Those expenses permitted will be limited to an additional $57,061.32, for a total of $129,889.29.

V. CONCLUSION

The Court has carefully considered the Plaintiffs' request for an exceptional case finding and for costs and attorneys' fees. Accordingly, this Court believes that Plaintiffs are entitled to reasonable costs and fees. Plaintiffs are entitled to an award of $138,880.46 in costs as the prevailing party. Plaintiffs are further entitled to $8,375,181.64 in attorneys fees and expenses under 35 U.S.C. § 285. Defendants are ordered to pay a total of $8,514,062.10 to the Plaintiffs. Accordingly,

IT IS HEREBY ORDERED that Plaintiff Monsanto's Motion for Costs [doc. #895] is granted. The Clerk of the Court shall tax costs in favor of Plaintiffs against Defendants in the amount of $138,880.46.

IT IS FURTHER ORDERED that Plaintiff Monsanto's Motion for a finding of exceptional case and for an award of attorneys' fees [doc. #898] is **GRANTED.** Defendants are ordered to pay attorneys' fees in the amount of $8,375,181.64.

Dated this 12th Day of April, 2007.

s/ E. Richard Webber
E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE

APPENDIX E — FINAL JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION DATED SEPTEMBER 25, 2006

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Case No. 4:00CV01915 ERW

MONSANTO COMPANY,

Plaintiff(s),

vs.

BAYER BIOSCIENCE, N.V.,

Defendant(s).

FINAL JUDGMENT

IT IS HEREBY ORDERED AND ADJUDGED that a jury has determined by its verdicts that as to Infringement, Bayer has not shown by a preponderance of the evidence that on or after August 13, 1996, Monsanto's MON 810 Bt corn has infringed any of the asserted claims of the '565 patent; that as to Prior Invention, Monsanto has shown by clear and convincing evidence that the asserted claims of the '565 patent are invalid because Dr. Fischhoff and Dr. Perlak at Monsanto invented the claimed subject matter before Bayer; that as to Obviousness, Monsanto has shown by

clear and convincing evidence that the asserted claims of the '565 parent are invalid because the claimed invention is obvious in view of the prior art; that no damages are awarded in favor of Bayer against Monsanto; and that Bayer has not shown by clear and convincing evidence that Monsanto's MON 810 willfully infringed.

IT IS FURTHER ORDERED AND ADJUDGED that as to equitable issues before the Court, U.S. Patents 5,254,799; 5,767,372; 6,107,546; and 5,545,565 are unenforceable due to Bayer's inequitable conduct during patent prosecution.

So Ordered this 25th Day of September, 2006.

s/ E. Richard Webber
E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE

APPENDIX F — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION AUGUST 28, 2006

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

Case No. 4:00CV01915 ERW

MONSANTO COMPANY,

Plaintiff,

vs.

BAYER BIOSCIENCE, N.V.,

Defendant.

MEMORANDUM AND ORDER[1]

This matter comes before the Court after a four-day inequitable conduct hearing, held February 21, through February 24, 2006. Closing arguments were heard on May 5, 2006. The Court is in receipt of Defendant's Trial Brief [doc. #844]; Plaintiff's Trial Brief [doc. #845]; Plaintiff's Supplemental Authority

1. The Court will assume the reader is familiar with the technology at issue in this case and the facts and procedural background appearing in this Court's January 10, 2005 Order pertaining to Monsanto's Motion For Summary Judgment Relating To Inequitable Conduct.

[doc. #847]; Plaintiff's Post-Trial Brief [doc. #863]; Defendant's Post-Trial Brief [doc. #869]; Plaintiff's Responsive Post-Trial Brief [doc. #874]; Defendant's Second Post-Trial Brief [doc. #877] and Bayer's Post-Trial Motion For Judgment As a Matter Of Law [doc. # 867].

FINDINGS OF FACT

This Court will be freely quoting from the testimony of Bayer officials and current and former employees of PGS[2] and Bayer[3] as well as Monsanto's witnesses. The deposition testimony of Marnix Peferoen was presented in Monsanto's case. His testimony frequently speaks of repeated negative test results in achieving insect control in Bt plants. It is unrefuted, that at the highest levels, and all levels of PGS, negative tests in Bt cotton, cabbage and corn plants was the norm, not the exception.

Dr. Peferoen, when he was deposed on May 23, 2002, was employed with Aventis CropScience, N.V., as leader for trade development for corn and cotton. He was responsible for all of the bioscience and biotechnology research activities associated with corn and cotton. When he started with PGS, he worked with others on

---

2. PGS is an abbreviation for Plant Genetic Systems, NV. PGS was later acquired by Aventis, which in turn, was, at least in part, acquired by Bayer.

3. All references in this opinion to Bayer, unless otherwise stated, include any company acquired by or alligned with Bayer in this litigation.

the Bt project. On May 8, 1991, he was in charge of the insect control project at PGS. He remained in control until the end of 1995. (Depo. desig. May 23, 2002 P.7. L.8-20; P.8 L.13-15; P.13 L.4-17).

Dr. Peferoen describes the function of the "Bt expression group" of PGS, headed by Dr. Cornelissen, was to develop technologies to express Bt genes in a proper way in plants. A separate group, headed by Arlette Reynaerts, was the "Bt plants group" which focused on engineering the genes into the plants. Yet another group, headed by Stephan Jansens, was the "entomology group" which provided service to the Bt screening element, and provided service to transgenic plants that needed to be tested with insects. Regular meetings of the insect control group were held beginning in 1987 "to exchange status of where we are in the different parts of the programme and where we go from here." (Depo. desig. May 23, 2002 P.14 L.8-P.15 L.9; P.23 L.2-16). These meetings were regularly attended by Dr. Peferoen, Dr. Cornelisson, Dr. Reynaerts, Mr. Jansens and Dr. Cardoen. If there were failures with respect to obtaining Bt expression in plants, that would be discussed. (Depo. desig. May 23, 2002 P.25 L.2-23).

Dr. Peferoen authored an article in May 1997, in *TIB Technology*, on plant protection from Bacillus thuringiensis which references, in a footnote, work performed by Dr. Vaeck relating to a truncated Bt2 gene being expressed in tobacco. The article also recognizes work of Dr. Fischhoff relating to insect-resistant tomato

plants. Dr. Peferoen recognizes that both Doctors Vaeck and Fischhoff "were at the forefront . . . with respect to expressing Bt genes in plants." (Pl. Ex.189) (Depo. desig. May 23, 2002 P.39 L.5-24; P.40 L.11-23). Dr. Peferoen recognized that to go from tobacco plants to other plants required substantial effort by research scientists. Referencing his article, Dr. Peferoen acknowledges that he was not aware of any commercial product that included a native truncated Bt gene. Based on the native truncated Bt gene technology, no one had been able to arrive at a commercial product. He wrote, "[t]he journey from concept to product proved to be formidable." (Depo. desig. May 23, 2002 P.40 L.24-P.41 L.25). Dr. Peferoen wrote, "[f]or several crops, expression levels of the crystal protein genes were too low and consequently the genes were modified in order to increase their expression." (Depo. desig. May 23, 2002 P.45 L.8-15). He was asked during his deposition, "[a]nd it was understood at PGS that the expression levels of the native truncated Bt2 gene were too low to arive at insect control in some plants?" He answered, "[i]n some plants, yes." (Depo. desig. May 23, 2002 P.45 L.22-25).

On April 14, 1989, in a memorandum to Dr. Peferoen from Geert Van Brandt, a PGS business development manager, Van Brandt writes, "[f]rom my discussion with Marnix [Peferoen] and Arlette [Reynaerts], it appears that the overriding bottleneck remains Bt expression." (Pl. Ex. No. 653)(Depo. Ex.15) (Depo. desig. May 23, 2002 P.86 L.7-19). Dr. Peferoen testified, "[t]hat's what it says." He acknowledges that as of April 14, 1989, Bayer had not developed an insect-resistant cotton plant

"probably not" at a commercial level. The memo recites, "[n]eedless to say, there is some urgency on this matter." (Depo. desig. May 23, 2002 P.87 L.17-20). Dr. Peferoen states that from the early Eighties, it was recognized that there was a problem with Bt expression in plants, and the issue of the "bottleneck" was discussed "sometimes" at the meetings.

Dr. Peferoen acknowledges receipt of a notice of a meeting in July, 1989, which states under part c, "[a]ll Bt genes indicate similar problems of expression in plants: Bt2, Bt3, Bt15; identifying and solving the bottlenecks in Bt gene expression is a key factor in the whole project." (Pl. Ex. No.659)(Depo. Ex.16) (Depo. desig. May 23, 2002 P.89 L.7-12; P. 90 L.4-19).

Around September, 1989, Dr. Peferoen made some notes at a meeting where groups were reporting expression of Bt genes. Kim Barton was with a company called Agracetus. Dr. Roy Fuchs was there for Monsanto. Both Barton and Fuchs, Dr. Peferoen acknowledges, reported on modified Bt genes and enhancing expression. Barton reported on how he changed the codon usage of the gene, and Fuchs talked about how he changed the DNA sequence resulting in no differences in the amino acid sequence. Dr. Peferoen understood "that to be involving plant-preferred codons." (Pl. Ex. No.661)(Depo. Ex.19) (Depo. desig. May 23, 2002 P.101 L.10-22; P.102 L.3-P.103 L3). Dr. Peferoen recognized that Mr. Jansens also attended the meeting for Bayer. On page two of his notes, Dr. Peferoen made a notation "mc." That did not suggest to him that

Dr. Marc Cornelissen was present, but that "he should take attention to this section," because, "Marc Cornelissen was looking in gene expression in general." (Depo. desig. May 23, 2002 P.103 L.5-10; P.104 L6-20).

Dr. Peferoen testified that as of May, 1990, he wrote, "[a] total of 13 cotton plants were tested on Spodoptera . . . and Heliothis . . . with negative results. (Pl. Ex. No.676)(Depo. Ex.26) (Depo. desig. May 23, 2002 P.146 L.18-P.147 L.16). This report was circulated to Dr. Reynaerts, Mr. Jansens and Dr. Cardoen. He recognized that these tests "observed no insecticidal activity" for the Bt2 gene involved. (Depo. desig. May 23, 2002 P.147 L.17-23).

In January, 1991, Dr. Peferoen wrote an agenda for a Bt meeting to be held on February 6, 1991. He outlined what should be discussed at the scheduled meeting. He was asked if he understood that someone at Bayer had tried to express Bt in cabbages to control Lepedoptera insects and failed. He answered, "[m]aybe." (Depo. desig. May 23, 2002 P.150 L.4-8). He knows that Dr. Reynaerts was involved with the Bt cabbages. He notes that Bayer has decided not to actively pursue the insect cotton market. At that time, Bayer had tried to express a Bt gene in cotton, and efforts showed no insect-resistance that he reported. (Pl. Ex. No.687)(Dep. Ex. 27) (Depo. desig. May 23, 2002 P.148 L.14-21;P. 150 L. 9-13:P.153 L.20-P.154 L.6). Dr. Wouter Meulemanns believed the reason Bayer was not going to pursue the insect cotton market was because Bayer was a small company which had to make priorities, so the decision

was business, not technically based. (Depo. desig. May 23, 2002 P.150 L.15-P.151 L.8; P.153 L.5-11).

On April 30, 1991, Dr. Peferoen prepared a memorandum concerning an insect control meeting scheduled for May 8, 1991. (Pl. Ex.691)(Dep. Ex. 28). He directed that others prepare reports. He says it is quite possible that Dr. Reynaerts prepared a report which is dated May 1991, in conjunction with this meeting. She reports that insecticidal levels of Cry1A(b)[4] were obtained in tobacco, potato and tomato but expression levels were insufficient to obtain insect control in brassica and cotton.

"She's not saying that expression levels were insufficient for commercial purposes, right?" Dr. Peferoen answered, "[n]o, she's not saying that." "She's saying insufficient to obtain insect control, correct?" He answered, "[t]hat's correct." (Depo. desig. May 23, 2002 P.154 L.8-16; P.156 L.17-P.157 L.9;158-L.7-24). Dr. Peferoen acknowledges that Dr. Reynaerts had experimented with tobacco and potato using wild-type (native) truncated Bt genes with positive results, but with potato a truncated CryIA(b) gene had been tried with insufficient results to obtain insect control. Dr. Muelemanns admits that the gene under the control of the TR2 promoter was insufficient to obtain insect control. Using the same promoter, with the CryIII(b) truncated gene in potato, insufficient insect control was obtained. In cotton, with the truncated Cry1(c) gene,

---

4. CryIA(b) gene refers to Bt2.

"that was insufficient to obtain insect control, right?" Dr. Peferoen answered, "[y]es, with the TR2 promoter." (Depo. desig. May 23, 2002 P.161 L3-162 L. 3).

With respect to corn, in a memorandum dated November 14, 1991, (Dep. Ex. 29) (Plaintiff Ex. 701), by Dr. Peferoen, page two reflects bioassays with corn borer upon a set of transgenic corn genes which showed "no significant insecticidal activity thus far." He answered, "[t]hat's what it says." He was asked, "[n]ow the gene you're working with is IA(b)6 in corn, correct?" He answered "[y]es." "This gives 50 times higher expression than a native truncated Bt2 gene, correct?" Dr. Peferoen answered, "[t]hat's in general terms." "And even with a gene that expresses so much greater, as of November 1981 *sic*, [1991] when you tried it in corn, you observed no insecticidal activity, correct?" He answered, "[i]n these 37 plants." He was then asked, "[w]ell, Dr. Peferoen, going back to P.29 for just one more question, the fact that the Cry1A(b)6 gene had been tried in corn and there had been no insecticidal activities had been (*sic*) reported at this November 14, 1991 meeting, correct?" He responded, "[y]es, at that stage, yes." "And it had been reported to the attendees of the meeting which include Ms. Reynaerts, Dr. Cornelissen, Mr. Jansens and Dr. Cardoen, correct?" Dr. Peferoen answered, "[m]m mm, yes (Depo. desig. May 23, 2002 P.166 L.20-P.168 L.2; P.169 L.13-24). Even after the Jansens' declaration was filed in the United States Patent Office, Bayer still had no success in gaining insect control in corn. This failure, along with many others, were not reported to the United States Patent Office.

Appendix F

A memorandum was generated on July 15, 1993, from Dr. Van Mellaert to recipients including Dr. Peferoen, discussing the strategic option for Bt gene Cry1A(b) expression in corn. Dr. Van Mellaert reports, "[i]t appears that at this stage we do not have much of a clue primarily because the appropriate tools are lacking for corn: no suitable transient assay is available in corn and stable transformation events are too few." (Pl. Ex. No. 729)(Dep. Ex.34) (Depo. desig. May 23, 2002 P.182 L.15-P.183 L. 13). The memorandum goes on to mention "smart Bt gene strategy" versus "synthetic Bt gene strategy." While "smart"[5] strategy is aimed at making very direct modifications in the gene sequence believed to have an impact on gene expression, the "synthetic" gene strategy refers to a more general modification throughout the sequence, according to Dr. Peferoen. The "synthetic" gene sequence had been reported by Monsanto in its patent application. When asked if he had reviewed it, Dr. Peferoen responded, "[s]ome of that, yes, but I think there are others in there that are not the entire modification throughout the sequence." (Depo. desig. May 23, 2002 P.185 L.2-P.186 L.8). Dr. Peferoen admits that he has never seen the smart gene strategy work in corn. (Depo. desig. May 23, 2002 P.188 L. 6-9).

In a memorandum to Dr. Peferoen and others regarding a corn meeting (Pl. Ex. 755)(Dep. Ex. 37)

---

5. The Cry1A(b)6 gene is an example of a smart gene. PGS started working on the smart gene strategy in the late 80's. Dr. Marc Cornelissen was working on that gene.

dated April 19, 1994, page 9 reveals the smart gene strategy pursued by Bayer. Page 15 reports 15 transgenic corn lines containing Cry genes, with a partially modified codon region, do not express Cry transcripts at detectable levels. (Depo. desig. May 23, 2002 P.202 L.24-25; P.203 L.12-20;P.204 L.2-19). This is a report on the smart gene strategy, and Dr. Peferoen recognizes that this experiment was unsuccessful.

Dr. Marc Cornelissen wrote a memorandum to Dr. Peferoen and others regarding a strategy meeting to be held on October 6, 1994. He references work relating to the Cry1A(b) Bt2 gene, concluding that initial studies performed in tobacco from 1989-1992 showed the truncated "1A(b)" coding region Bt884[6] is inefficiently transcribed in vetro. The memorandum speaks of Cry1A(b) tests in corn in 1991 and 1993, and under the 1993 reference, it says, "[t]he transformants analyzed did not express a detectable level of IA(b) mRNA. Dr. Peferoen was asked, "[a]nd if it's not expressing a detectable level of IA(b) mRNA, that means that you're not going to get insect-resistance, correct?" Dr. Peferoen answered, "[m]ost likely." (Depo. desig. May 23, 2002 P.204 L.21-P.205 L.2;P205 L.16-P.206 L.6;P.207 L.7-P.208 L.9). By the end of 1993, Dr. Peferoen admits, that regarding these experiments, Bayer's Bt corn work had not observed a detectable level of the Bt gene. This was, of course, more than two years after Mr. Jansens' September 9, 1991 declaration. This information was not submitted to the United States Patent Office.

---

6. Bt884 is a truncated native Bt2 gene.

Appendix F

The '799 patent was filed January 1, 1986, and seven years later, Dr. Peferoen was asked, "after all this work at PGS that we have been talking about today, the conclusion was that they still had not observed detectable Bt expression in corn?" He answered, "[y]es." (Depo. desig. May 23, 2002 P.209 L. 3-7). Bayer did not use a Bt2 gene in Starlink, its first Bt corn product, but instead used a Cry9c fully synthetic gene instead of a Bt2 gene that Vaeck discussed in the *Nature* article in 1987 (Depo. desig. May 23, 2002 P.221 L. 5-19).

Dr. Marc Cornelissen was deposed on the 29th day of May 2002, when he was employed at Aventis CropScience, N.V., in Ghent, Belgium, as team leader for technology discovery. He has worked for Aventis since 1984. He describes his technical expertise as gene expression in plants. He worked with Bt expression in plants from 1988 to around 1996 or 1997. (Depo. desig. May 29, 2002 P. 5 L.18-P.6 L-2; P.8 .14-19; P.9 L.6-17; P.10 L.100-18).

In a progress report written by Dr. Cornelissen in March 1990, regarding expression levels of different Bt2 plant genes, he says, "[t]he results of this experiment were negative in the most absolute sense of the word." He was asked, "[t]he Bt level directed by the Bt gene was never sufficiently high to be detected in the quantative Elisas?" He answered "[y]eah." (Pl. Ex. No. 924) (Depo. Ex.72) (Depo. desig. May 29, 2002 P.129 L.18-21; P.132 L.14-18; P.133 L.18-P.134 L.2).

Appendix F

In a memorandum prepared by Dr. Cornelissen in August 1990, he wrote, "[t]he construction of a modified Bt2 coding sequence will be given higher priority." (Pl. Ex. 928) (Depo. desig. May 29, 2002 P. 137 L.23. -P.138 L.6; P.139 L.12-16). A decision was made to construct a completely artificial coding sequence with a plant codon usage in September, 1990, for the first time. He does not recall if he had information that Monsanto had already done this. However, when shown Plaintiff's Exhibit no. 681, (Depo. Ex. No. 23), a memorandum prepared by Dr. Cardoen, which Dr. Cornelissen admits he received, he admits that Dr. Cardoen reported to him that Monsanto had already disclosed in its patent application the removal of ATTA sequences.[7] He was asked, "[a]nd so your approach to reduce the As and Ts of the Bt gene is consistent with what Monsanto was suggesting in its patent application, correct?" He asked a question and in response asked, "[w]hat do you mean is 'inconsistent with?'" He was then asked, "[w]ell, you were going to reduce the ATs. Do you remember we saw that?" He answered, "[i]t is similar as an action." (Depo. desig. May 29, 2002 P.148 L.18-P.149 L.11; P.150 L.17-P.152 L.11). He admits that in September 1990, his group was setting out to make a fully synthetic truncated Bt gene, and Monsanto had already accomplished making a fully synthetic truncated Bt gene that showed expression in plants. Specifically, the following questions and answers are recorded.

Q. In any event, you were setting out, in September of 1990, to make a fully

7. This process enhanced Bt expression.

synthetic truncated Bt gene, correct, your group? And so far as the information that was reported to you within PGS, Monsanto had already accomplished making a fully synthetic truncated Bt gene, correct?

A. Yeah.

Q. And it already had shown expression in plants, correct?

A. That is what this report says, yep.

(Depo. desig. May 29, 2002 P.156 L.11-22).

In March 1992, Dr. Cornelissen issued a report on the status of the Bt corn project as of January, 1992. He states, "it is not clear if the low expression level is related to the presence of the Cry gene and/or if it is linked to inefficient expression of the Cry gene." (Pl. Ex. No. 709) (Depo. Ex. No 78) (Depo. desig. May 29, 2002 P.167 L. 17-20; P.168 L.25; P.169 L.1-5; P.170 L.20-P.171-l.3). On October 8, 1993, Dr. Cornelissen prepared a document referencing the Bt strategy meeting that took place on October 8, 1993. He was asked, "[a]nd the objective, still 8 years after the '799 patent was filed, was development of a proprietary IA(b) gene expressing adequately in corn, correct?" He answered, "[t]hat's what it says." (Pl. Ex. No. 740)(Depo. Ex. No. 86) (Depo. desig. May 29, 2002 P.228 L.3-20). In the same exhibit, Dr. Cornelissen says, "[t]he transformants analyzed did

not express a detectable level of IA(b) mRNA." It took Bayer until 1996, or thereafter, to construct a CryIA(b) gene that would express insecticidal levels in corn. (Depo. desig. May 29, 2002 P. 270 L.23-P. 271 L.7).

Dr. Wouter Meulemanns was deposed March 20, 1998; July 16, 2002; August 13, 2002; and August 14, 2002. He is employed by Bayer CropScience, NV, living in De Pinte, Belgium. He has a "kind of master's degree" in biology and a Ph.D degree in biology, specializing in zoology, particularly in cell biology analysis of cytokeleton developments in insect renal tubules. He was awarded the Ph.D degree in 1992, the year he became an employee of Bayer. From then until the present time, he has been working in the intellectual property department with responsibilities which "include assisting attorneys with prosecution of patent applications." (Depo.desig. July 16, 2002 P.7 L.9-10). He was asked if he understood this case involved four patents; he said he did and that they were included as his responsibility as soon as he started to do actual work after his training. He assumed the responsibility for overseeing the four patents after Johan Cardoen left the Company probably sometime in 1993. His training primarily consisted of conversations with outside counsel, conversations with people in the office and maybe attending some courses. Part of his training included familiarizing himself with the work that had been done at Bayer with regard to expressing Bt genes in plants. He expects that he read the patent applications for the patents in suit, but he does not recall if he looked at the file histories of the patents in suit. (Depo. desig. August 13, 2002 P. 14 L.3-7).

Appendix F

Dr. Meulemanns was shown, and, he identified the Jansens' declaration. (Joint Trial Ex. 6). He does not recall if he reviewed it before the '799 patent issued. He does not recall when he first looked at it. He does not recall specifically if he ever discussed the declaration with Mr. Jansens (Depo.desig. August 13, 2002 P.69 L. 8-23). Dr. Meulemanns was shown the following language from the Jansens' declaration, "[t]he test results shown in appended Figs. 1 through 11 demonstrate that any truncated Bt gene can generally be used to provide an insect-controlling amount of the encoded Bt polypeptide toxin in generally any plant transformed with the truncated Bt gene." When he started attending meetings of the Bt group in 1993, he does not recall if he became aware of "any final results which would seem to indicate that this would, that there would be contrary to this conclusion" (Depo.desig. August 13, 2002 P.70 L11-P.71 L.2). He was asked if he became aware of experiments showing that corn transformed with the truncated Bt gene did not demonstrate any insect control. He said, "I don't recall specifically but I think you always get negative results in any transformation effort that you undertake so I cannot exclude that we had negative plants." (Depo.desig. August 13, 2002 P.72 L.20-P.73 L.2). Dr. Meulemanns was then shown several exhibits and made comments and conclusions.

Plaintiff's exhibit 723 (deposition exhibit 200) is a notice regarding a Bt meeting for February 5, 1993. He was asked if the purpose of the meeting was to understand what scientists were doing in the Bt field. He answered, "[c]ould have been, yes." (Depo.desig.

August 13, 2002 P.15 L. 20-P.16-L.9; P.19 L.4-7). Plaintiff's exhibit 738 (deposition exhibit 209) is a memo from Herman Van Mellaert dated October 6, 1993, copied to Dr. Meulemanns. Van Mellaert says, "[s]ince we have not yet reached workable Bt expression levels in corn and since there have been several statements that expression strategies worked out in dicot systems are unlikely to work in corn" (Depo.desig. August 13, 2002 P.83 L.11-15). Dr. Meulemanns testified that he did not know exactly that the patent examiner had allowed the '799 patent based on the Jansens' declaration. When he knew that the '799 patent was going to be issued shortly, he does not recall what occurred to him at that time relative to disclosing this information to the United States Patent Office. When asked why he did not submit it, he said, "I don't know any information which is reflected with these statements, by these statements, so" (Depo.desig. August 13, 2002 P.85 L.10-P.86 L.16).

Plaintiff's exhibit 967 (deposition exhibit 210) is a report from Marc Cornelissen dated October 8, 1993, of which Dr. Meulemanns was a recipient. Under status, it says, "[s]ince 1991, five different transforming DNAs were stablely inserted into corn." Then, at the bottom of the page, "the conclusion was the transformants analyzed did not express a detectable level of 1Ab mRNA." Dr. Meulemanns said, "[t]hat's what the document says, yes." (Depo.desig. August 13, 2002 P. 87 L.21-P.88 L.24). The following questions and answers appear:

Q. Now this is a negative result, correct?

A. This appears to be negative results for detectable levels of 1Ab mRNA in certain transformants.

(Depo.desig. August 13, 2002 P.88 L.25-p.89 L.3).

Dr. Meulemanns admits that these results were not communicated to the United States Patent Office before the '799 patent was issued; he believes that the results were not a final analysis; when asked if this report represented three years of work he said he did not know. These questions and answers are reported regarding transgenic corn plants reflected in Plaintiff's exhibit 967:

Q. If we add these all up for 1991 and 1992, there's a total of 30 independent transformants that were obtained, correct?

A. Probably approximately 30.

Q. And none of them expressed a detectable level of CryIA(b) mRna correct?

A. It says the transformants that were analyzed did not express the technical level of CryIA(b) mRNA. I don't know which of those were re-analyzed.

Q. And the fact that the analyzed transformants did not express a detectable level of CryIA(b) mRNA, you didn't disclose that to the Patent Office?

A. For this specific transformants in the document 9-210 [p-210 deposition exhibit is Pl. Ex. 967].

Q. Yes.

A. Indeed, yes.

Q. Yes, you did not disclose that to the Patent Office?

A. Yes.

(Depo.desig. August 13, 2002 P.91 L.21-P.92 L.16).

Plaintiff's Exhibit 741 (deposition exhibit 211) is a memorandum from Dr. Van Mellaert dated October 11, 1993, wherein Dr. Meulemanns is an addressee. The memorandum is in respect to a Bt strategy meeting dated October 8, 1993. Dr. Meulemanns was asked if this meeting was after it was learned that the '799 patent was going to issue but before the issue date, and he replied that he did not know for sure that the '799 patent was going to issue. Dr. Meulemanns agrees that on page one, one of the topics for discussion was whether a rational Bt gene expression strategy is possible in corn. He was then shown part of the Jansens' declaration and

the record states that the examiner was told that there were results which demonstrated "that any truncated Bt gene can generally be used to provide an insect-controlling amount of the encoded Bt polypeptide in generally any plant transformed with the truncated Bt gene, correct?" He answered, "[y]es." When asked if the discussion topic in Plaintiff's Exhibit 741 and this part of the Jansens' declaration were inconsistent, Dr. Meulemanns disagreed that the topic of discussion and the partial statement from the Jansens' declaration are contradictory. He said he did not know if the patent examiner was ever told about the difficulties Bayer was experiencing expressing a truncated Bt gene in corn. (Depo.desig. August 13, 2002 P.92 L.21-P.96 L12).

Plaintiff's exhibit 526 (deposition exhibit 57) reflects Dr. Mariani's notes taken from a poster on display at a booth occupied by Dr. Wayne Barnes at the First International Congress of Plant Molecular Biology in Savanna, Georgia in 1985. Dr. Meulemanns, characteristic of his testimony when asked questions which invite damaging information against Bayer replied "I don't recall" to the question as to when he first saw the notes. (Depo.desig. August 14, 2002 P.305 L.5-7). Time after time in his testimony, it is apparent that Dr. Meulemanns engages his selective memory upon command. He doesn't "exactly" know how the notes were brought to his attention, but admits they were written by Celestina Mariani, who obtained them from a presentation. He was shown Joint Trial exhibit 9, page 1865, which is an office action that he would review. (Depo.desig. August 14, 2002 P.319 L.4-6). The Wayne

Appendix F

Barnes' abstract which was cited to the PTO examiner is different than the Mariani notes, which were not submitted to the examiner. He was asked if the Barnes' abstract "is cited to show that the use of a Bt gene to encode a fusion polypeptide was well known. The fusion protein encoded a selectable marker which was neomycin phosphotransferase." He confirmed that he was observing that. (Depo.desig. August 14, 2002 P.319 L.3-15). He was then shown Joint Trial exhibit 9 (deposition exhibit 59), an office action from the file history in the '372 patent. Page 1881 reflects, "[t]he further application of Barnes et. al. is believed to be unavailing. Barnes et. al. is cited to show that the use of the Bt gene to encode the fusion polypeptide with a selectable marker which is neomycin phosphotransferase." Dr. Meulemanns acknowledged seeing that exhibit. Then he was shown the next paragraph, "[I]nitially, applicants note that the Barnes' Abstract merely *speculates* about the possibility of replacing the second half of the Bt toxin gene with codons of the NPTII selectable marker gene (emphasis added)." Dr. Meulemanns acknowledges that the Barnes' abstract does not disclose a gene in which the second half of a Bt toxin gene has been replaced with codons of the NPTII selectable marker. He also acknowledges that the Barnes' Abstract does not disclose a gene construct containing both the Bt gene and a Kanamycin resistance gene in which both genes are expressed. Bayer submitted the Barnes' abstract and told the PTO examiner that the Barnes' abstract speculates regarding replacing the second half of the Bt toxin gene and admits that the Barnes Abstract does not disclose a gene

construct containing both the Bt gene and a kanamycin resistence gene in which both are expressed. The Barnes notes, which were not disclosed, were known to be distributed among officials and employees at Bayer.

When shown Plaintiff's Exhibit 526.1, the Mariani notes, he was asked, "is there a disclosure there of a gene construct containing a Bt gene fused to the Kanamycin resistence gene?" He answered, "I don't know for sure." (Depo.desig. August 14, 2002 P.319 L.21-P.324 L.17). Thereafter, the following questions were asked and the following answers were made.

Q. Is there a suggestion of a construct containing the Bt gene fused to Kanamycin resistance gene on the notes on D-57 [Pl. Ex. 526], in the notes on D-57?

A. Maybe that is a conclusion that could be drawn from these notes.

Q. And could that be interpreted to indicate that the construct that is drawn on this page expresses both Kanamycin and a toxic Bt protein, is that one possible interpretation of the notes on this page?

A. I guess we have been discussing several potential interpretations of several potential constructs.

Appendix F

Q. Is one possible interpretation of the notes on this page that a construct was made in which the Bt gene was fused to a gene for Kanamycin resistance?

A. That is a possible interpretation.

Q. It is one possible interpretation of the notes on this page that the construct expressed a protein conferring Kanamycin resistance?

A. There is a reference to a statement which could be interpreted as being KM is not expressed and KM is expressed, but I don't see any direct reference to any resistance to Kanamycin of a particular construct.

Q. But there is a reference to an expression of Kanamycin, is there not?

A. There seem *sic* to be the words on these notes which cited KM is expressed, yes.

Q. Is one possible interpretation of the notes on this page that the construct expressing the protein conferring Kanamycin resistance also expressed a protein which was toxic to larvae?

A. Well, there is a statement which could be interpreted as saying KM is expressed and it, probably referring to KM, is toxic for larvae as drop.

Q. That's a possible interpretation of these notes, isn't it, that Dr. Barnes did indeed make a chimeric gene in which the Bt gene was fused to the Kanamycin — to a Kanamycin resistance gene and that both the Bt protein was expressed such that toxicity to larvae was observed, and the Kanamycin resistance gene was expressed such that Kanamycin resistance was observed?

A. You could make that assumption.

(Depo.desig. August 14, 2002 P.325 L.6-P.338 L.3).

Dr. Meulemanns was asked to look at the bottom of Plaintiff's exhibit 526 where it says "toxins 67 Kd." He replied, "it could be interpreted as toxin 67 or toxin 61 Kd." He was then asked, "[l]et me rephrase the question. Are you aware of Bt2 toxins having a size of 61 to 67 Kd which are toxic to insects?" He answered, "[y]es." (Depo.desig. August 14, 2002 P.338 L. 24-P.339 L.19). When it was suggested to Dr. Meulemanns that Plaintiff's exhibit 526 could be interpreted in such a way to directly contradict the representation that was made to the Patent Office that Barnes merely speculates about the possibility of forming a chismeric gene by

reproducing the second half of the Bt gene with the gene for Kanamycin resistance so both activities could be expressed, Dr. Meulemanns answers, "[t]hat is what you say." When asked if it could be interpreted in that way, Dr. Meulemanns responded, "[y]ou have asked me I don't know how many terms which have possible interpretations and were very vague in combining all of those terms, you come up with a possible interpretation which would then say that directly contradicts a statement made on page 10." (Depo.desig. August 14, 2002 P.344 L. 4-17). He was then asked, "[d]o you think this would be important to a patent examiner who was looking at whether or not the representations that PGS made about Barnes' presentation was accurate?" Dr. Meulemanns answered, "[i]f these notes would add anything of reliable information which could add to the abstract, that could be important." He agreed that if the information was important, the patent examiner had no other way to get the information unless "you" provided it. (Depo.desig. August 14, 2002 P.345L.6-23).

Dr. Meulemanns' responsibilities in assisting attorneys representing Bayer in filing and prosecuting patent applications included the '799 patent and the '565 patent. He does not know when he became aware of the 1985 Barnes' presentation, but it must have been, he says, during the prosecution of the '565 patent. He saw Dr. Mariani's notes, recalls them, and knows that the notes "said something to the effect of the construct was toxic as a drop but not when in plants." (Deposition read into record trial Tr. Vol. III Part A P.5 L2-P.6 L.1). Upon further examination, he testified that he did not know

whether he could draw the conclusion that Barnes had put Bt into plants. He said, "[i]t may have been plant cells or plants, I don't exactly recall." (Deposition read into record trial Tr. Vol. III Part A P.5 L.19-20). Dr. Meulemanns remembers that he talked to Dr. Mariani about the Barnes notes and presentation. He was asked to describe what they discussed. He responded," I asked what she remembered from the proceedings, and she could not remember anything concerning the presentation or poster." (Deposition read into record trial Tr. Vol. III Part A P.6 L.2-21). Dr. Mariani's testimony stands in sharp contrast to that of Dr. Meulemanns. While in front of the poster, Dr. Mariani made a drawing of the same schemes presented on the poster. She is very clear in her description of her notes. In her testimony, concerning those notes, contrary to the testimony of Dr. Meuelmanns, Dr. Mariani recalls a great deal about the notes and in her deposition testimony is very articulate in describing what she saw.

Q: . . . . . This document we have marked as Mariani Exhibit 5, [Pl.Ex. 526.1] do you recognize the handwriting?

A: Yes, I recognize my handwriting.

Q: This is your handwriting?

A: It is, yes.

Appendix F

Q: This is a copy of the abstract, your abstract book, where you had handwritten notes?

A: Yes, it is, yes.

Q: Did you handwrite these notes while you were looking at the poster or later?

A: Yes, I was in front of the poster and I made a drawing of the same schemes that were presented on the poster, using slang and short cuts.

Q: It seems one of the first things that you wrote, you drew a rectangle. Was that a representation of a gene?

A: Yes, this rectangle is the representation of a coding sequence of a gene in which I have also drawn the lesions.

Q: And in 1985, when you drew that, you thought that your colleagues would understand that you were representing a gene?

A: Perhaps with my interpretation but should be understandable, yes.

Q: Above that rectangle you have written '3.4K'.

A: Yes.

Q: What did you mean by 3.4K?

A: This made, as it is written like this, K, I can't remember any more, I think it is 3.4 kilo basis. K may stand for kilo basis or kilo Dalton. It represents a gene. I would assume I meant kilo basis.

Q: Then you have apparently crossed out the right hand part of the gene?

A: Yes, the right hand, all these crosses represent the lesions. The cuts represent the lesion, and so what I mean to say is that the lesion, the largest block to the left in which the right part of the gene has been eliminated, this would represent a soluble protein.

Q: Can you just take this blue pen and circle the part of that gene you were talking about when you said the right hand part of the gene?

A: Yes. So by eliminating this part of the gene, you are left with this part of the gene, and this would make a soluble protein.

Q: Just next to that first circle you drew, can you just write a number 1 and put your initials next to it?

A: So eliminate 1, you are left with two and that makes three, that is okay?

Q: Okay. So you were representing that if the gene, the portion of the gene that you circled a labelled number 1, was deleted and you were left with a portion of a gene where you wrote number 2?

A: That is still active.

Q: Still active you meant the protein would be still toxic to insects?

A: Yes.

Q: And you wrote underneath that gene 'xho', is that correct?

A: Xho represents one restriction site, one enzyme that was used probably to make the lesions, and psd is the other one.

Q: What you have drawn and just described to us is consistent with what the abstract said?

A: Yes, at least in the first part of it, talking about a lesion, the second half of the Bacillus. So number one circled would represent the second half of the Bacillus thuringiensis toxic gene, and if you remove that you have a still active and a soluble protein.

Q: And by writing in the xho site you are indicating a specific place where the gene was cleaved, is that correct?

A: Yes. Definitely that this site was there, but I do not remember exactly if that is the very last restriction site that it was used.

Q: But it would be very close?

A: Yes, probably would be, yes.

Q: Very close?

A: Yes, it would be.

Q: And that was information that was on the poster?

A: Yes.

Appendix F

Q: Below that, where you had written 'soluble protein', there is another rectangular representation of a gene, correct?

A: Yes.

Q: Can you tell us what you were describing in that gene?

A: Well, this is probably what is left over. So the 3.4 kilo basis, the block number 2, or the Bt gene, and this would make, once it is translated, would make a soluble protein.

Q: Yes, now just below that?

A: Oh, below that, okay. If I go below that, what I see here is a fusion between this part of the gene, so block number 3, that is in fact the part the soluble protein fused at the xho site that was used before to cleave it and coded for the kanamycin resistance.

Q: That is the NPT II genes?

A: Yes, that would be the NPT II genes.

Q: The left hand?

Appendix F

A: That is, I guess that is Bt promoter.

Q: So in this gene construct there was a Bt promoter, a truncated Bt gene, fused to the NPT II gene?

A: Yes.

Q: And the fusion between the Bt gene and the NPT II gene was at the xho site?

A: Yes, that is what it says.

Q: Just to the right of that you have some text.

A: Yes, it says out of frame kanamycin is not expressed. So that means that when the fusion is made out of frame, so that in fact the protein is really shifted, then the kanamycin is not expressed. And then it says: The kanamycin is expressed and it is toxic for larvae as a drop. If it is in frame then the kanamycin gene would be expressed and the construct would still be toxic to the larvae if used in a drop assay.

Q: Can you just circle the line and tell us verbatim what it says?

A: This one, the one we were just talking about?

Q: Yes. Read now what it says.

A: It says: Kanamycin is expressed and it is toxic for larvae as a drop.

Q: What that means is?

A: It is jargon. It means that the kanamycin, so the NPT II gene, is expressed and translated, and this confers resistance to the kanamycin, and when this construct is used in a feeding assay together in a drop really to the larvae, this would be toxic to the larvae, meaning a Bt gene is toxic.

Q: So the protein that is expressed is both toxic to insects, and it produced —

A: And it confers kanamycin resistance.

Q: Then you have an arrow down.

A: Yes.

Q: Can you just read, as best you can, from the copy what that says.

A: It says: But this construct is not toxic if it is in leaves. That is what it says. And I must assume that 'in leaves' then means they have done plant transformation, but I cannot remember exactly, to be honest. I mean I don't remember the issue of whether they do have NPT plants or not, but what I wrote is 'in leaves', so I would assume so.

Q: Are you referring still to the construct?

A: The fusion construct.

Q: With the Bt promoter?

A: Yes, the same one that is indicated up there. I guess so, yes.

Q: Just below that there is another sentence.

A: Then it says: Does not know how much Bt protein produces. So it means that in fact the author of the poster did not know how much of the protein was expressed in leaves then.

Q: Did you have any discussion with the author of the poster?

A: Yes, I remember somebody standing there but I can't remember if it was really the real author or somebody else for him. I really can't remember, but I remember talking to a person who gave extra information.

Q: I would like to go to the far left hand margin and ask you if you can tell me what you have written there. First I ask you, is this a representation of a chimaeric gene?

A: Yes, it is, and it is a chimeric gene placed into a T-DNA: On the left I have indicated right border, although it is on the left it is the right border for the T-DNA, and here, if we start from the right border, I have indicated the promoter of the nopaline synthese gene, the nors promoter, followed by the ATG.

Q: Sorry, I am going to just ask you to stop. We are going back to the numbering system, if you don't mind. Could you circle where you said what is the right border.

A: Okay, we start from the right border, on this picture on the left.

Appendix F

Q: Maybe we will number that 10, because I forget where we left off. So what you have circled as 10 indicates right border of a T-DNA?

A: Yes. Then next to the right border there is the nopaline synthese promoter.

Q: Circle that as 11. So you indicate number 11 is the promoter from the nopaline synthese gene?

A: Yes, followed by some translation sequences of the nopaline synthese gene, which are the ATG and the Shiner Dalgardo sequence.

Q: And that you are labelling 13?

A: 12.

Q: 12, okay.

A: And this is followed fused probably at the xho site, because the xho site is again indicated by an arrow, followed by the ATG of the first ATG of the Bt gene. So here there are two ATG's but they are both in frame. That is what it means in our jargon. And after the second ATG, the one of the Bt gene, follows the toxin, the Bt toxin gene.

Q: Can you circle where it says 'toxin'?

A: And that would be 67 KT [67Kd]. So the Bt gene is block 14.

Q: And the gene code for a toxic protein, that is 67 kilodaltons?

A: Yes.

Q: Kilodaltons is a common way to measure the molecular weight of a protein.

A: Yes molecular weight. After this toxin 67 KD fragment gene, whatever, there is four amino acid deletion. So it indicates that there is a small deletion of four amino acids.

Q: From the NPT II gene?

A: I don't know. It could either be from the Bt but it is not better identified. I would assume it is from the Bt2 because the end of the toxic gene is not given, but it says a deletion of four amino acids — this is block 15. And then it is followed by the gene, the NPT II gene, that confers kanamycin resistance. And I did not draw the end of this construct.

Appendix F

Q: And the end of the construct would have the rest of the nopaline synthese gene?

A: Probably would have the three prime end of the nopaline synthese gene, mentioned before in the abstract, that is one of the regulatory transcriptional control signals and would have the left T-DNA border.

Q: So it would have a three prime non translated region from the nopaline synthese gene.

A: Yes.

Q: That was additional information that was in the poster?

A: Yes, that was in the poster.

Q: That was not in the abstract?

A: Yes, definitely.

Q: So the poster had much more information than the abstract itself had?

A: It is always so.

Q: I want to go back to the statement where it says 'in leaves'. Do you know how the whatever Bt gene it was put into leaves?

A: I don't remember, but what I gather now, looking at this abstract, is that they may have tried in plants to introduce the Bt promoter fusion that is here, and this did not work. But they surely were busy with introducing in plants this cassette, this construct that is shown here on the left side, because otherwise there would be no reason to do the cloning within the right border and left border.

Q: And they were using Agrobacterium as a method of transforming plant cells?

A: Yes, here it is not mentioned in my notes, but I think so. My guess is so, yes.

Q: That is the reason to put in a T-DNA?

A: Yes exactly, and surely by that time our bacterium would be the most convenient and most used way of transformation.

(Depos. desig. May 30, 2002 P.29 L.9-P.44 L.13). More of Dr. Mariani's testimony will be included later.

It is very obvious that the poster notes, if they were disclosed to the patent examiner, which they were not, would stand in sharp contradiction to the Bayer argument before the patent examiner. The poster notes were widely circulated among the Bayer Bt groups. The Court finds from all of the evidence in the case, that

Appendix F

Bayer had a duty of candor and good faith to disclose the Mariani notes and intentionally withheld the information from the United States Patent Office examiner in the prosecution of the '565 patent with the intention to deceive the PTO examiner.

Dr. Arlette Reynaerts testified in Monsanto's case by video deposition. She now works for Aventis CropScience under the supervision of Dr. Peferoen in corn and cotton trait development where she heads the group for transformation. She was trained as a botanist at the University of Ghent. She was awarded a Ph.D degree in 1974. She began working in plant transformation in 1983 at the University of Brussels. Her career started with Bayer in November, 1984. In the summer of 1985, she became head of the plant transformation project. Plants under her area of control, for all of the routine transformations, were tobacco, cotton, potato and tomato. Because corn was a new transformation method that "had to be developed," there were other scientists appointed to work on corn. "Corn was not a routine transformation at that period." She testified that worldwide routine transformation of corn was not known in 1986 when she was head of plant transformation at Bayer. (Depos. desig. May 30, 2002 P. 5 L.20-P.6 L.9; P.6 L.24-P.7 L.13; P9 L.7-8; P.17 L.11-23; P.18 L.6-P.19 L.12; P19 L.21-P.20 L.2).

Minutes recorded by Marc Vaeck of a December 4,1986 Bt meeting show attendance of patent inventors, Dr. Vaeck, Dr. Montagu, Dr. Zabeau, Dr. Hofte and Dr. Jan Leemans. Under "summary of obtained results,"

Dr. Vaeck reported that Bt toxin levels in engineered tobacco plants was still relatively low compared to other proteins expressed in transgenic tobacco. (Pl. Ex.579)(Dep. Ex.93). He reports, and Dr. Reynaerts confirms, "[t]he reasons for this are not understood." (Depos. desig. May 30, 2002 P.56 L.8-P.57 L.12).

Rohm and Haas, a company located in the United States, provided funding to Bayer for selected Bt projects. A joint research report to Rohm and Haas from Dr. Reynaerts and Jan Leemans reveals that gene expression reported for these experiments that were carried out between December 1987, and March 1988, "have shown that the limiting factor on Bt production is not the efficiency of translation initiation on the Bt mRNA, nor the stability of Bt in plant cells." (Pl. Ex.630 p. 17). Dr. Reynaerts confirms that Bayer still had not, by March 1988, identified the problem with low Bt expression and by April or May, 1988, they were still suggesting further research was necessary to identify what the problem was for Bt expression. (Depos. desig. May 30, 2002 P. 72 L. 16 - 23). By January 1989, a report to Rohm and Haas prepared by Dr. Reynaerts, shows that Bayer scientists were still researching whether by mutation, Bt levels could be increased. (Pl. Ex. 646) (Dep. Ex. 96 p. 2). From 1985 through 1992, Dr. Reynaerts was directly involved in making Bt plants at Bayer.

Bt group meeting minutes, shown as being headed by Dr. Reynaerts on October 30-31, 1989, report that the group had success with tobacco Hornworm control in tobacco, but no tobacco Budworm control. There was

potato Tubor Moth control but no Colorado potato beetle control. Tomato Fruit worm control in tomato appeared doubtful. "Targets escape on cabbage and cotton." She reported there was not adequate control in cabbage and cotton. Mr. Jansens performed the insect tests and reported the results. (Pl. Ex. 665) (Dep. Ex. 24).

Dr. Reynaerts prepared a report in May 1988, showing that ten Brassica (cabbage) plants were transformed with a Bt860 gene construct that were evaluated in an insect assay, and with this truncated native Bt gene, this experiment did not express at a sufficient level to have any insect-controlling effect on these insects in cabbages. (Pl. Ex. 623) (Dep.Ex.55). Specifically, the report states, "[n]o effects were observed."

Dr. Reynaerts, on December 19, 1989, reports a cotton experiment that Bayer was testing with a Bt15 gene which showed no expression at sufficient levels to give any insect control. (Pl. Ex. 677) (Dep. Ex. 52). In May 1990, Dr. Reynaerts reports on experiments of cotton at PGS up to that time. Her report states, "[s]ince cotton transformation became available, a number of transgenic plants have been generated, transformed with different chimeric Cry1A(b) constructs." She concludes, "Elisa[8] performed on embryogenic cultures never gave any positive signal," Also, "[a]ll insect assays were also negative." (Pl. Ex.669) (Dep. Ex.No. 53)

---

8. Elisa is a test to measure presence of protein.

(Depos. desig. May 30, 2002 P. 93 L.20-P.95 L.25). She confirmed that Mr. Jansens did these tests. In a collection of the Bt group meeting minutes, Dr. Reynaerts concludes in her work with the Cry1A(b) Bt gene, there was no control of white cabbage moth in brassica and no boll worm control in cotton (Pl. Ex. 642 last page) (Dep. Ex. 97). Dr. Reynaerts observes, in a report of Dr. Peferoen cataloging an April 25, 1990 meeting, that in a test of 13 cotton plants on two insects with Aventis Bt genes, they did not express at levels sufficient to control these insects in cotton plants. The report states, "[a]fter cotton plants with fusion proteins have been tested, we will stop evaluating cotton plants." (Pl. Ex. No. 26 P. 2) (Depos. desig. May 30, 2002 P.98 L.18-P.99 L.17). She does not remember why the cotton research stopped. It appears from this exhibit, that it stopped abruptly with no assigned reason.

Dr. Peferoen announced a meeting of Bayer's insect control group to be scheduled May 8, 1991, stating, "[t]his meeting is not another presentation meeting. You have been invited to participate actively. The question of target crops will be raised again and is quintessential for the RND activities." (Pl. Ex. 641) (Dep.Ex. 28) (Depos. desig. May 30, 2002 P.101 L.23-P.102 L.21). Page two of that report was prepared by Dr. Reynaerts. She concluded that as of May 8, 1991, four months before the Jansen's September 9, 1991 declaration, based on testing she had done, the Bt fusion or truncated wild-type, the native genes that Bayer had, the expression levels of those genes were insufficient to obtain insect control in cabbages and cotton. She was asked, "[n]ow

these reports that we've been looking at with respect to your work on Bt plants in cabbages and cotton, this work would have been known to Stephen Jansens, correct?" She answered "yes." She was asked, "[b]ecause he would have done the bioassays?" She answered, "[y]es." (Depos. desig. May 30, 2002 P.104 L. 16-23). She confirmed that he did the insect bioassays and he would have known that the Bt genes, the truncated and the fusion Bt genes, did not express at levels sufficient to give insect control in cabbages and cotton. Specifically, these questions were asked and these answers given:

> Q. And he would have known that the Bt genes, the truncated and the fusion Bt genes did not express at levels sufficient to give insect control in cabbages and cotton, correct?
>
> A. Yes.
>
> Q. These reports were also circulated to a Dr. Cardoen, correct?
>
> A. Yes.

(Depos. desig. May 30, 2002 P.104 L.24-P.105 L.7).

Dr. Reynaerts described Dr. Cardoen as a collaborator in the technology protection department and that these referenced reports were circulated to him. She confirmed that he was sort of the Bt projects

patent guy who would have known as of May 1991, that the truncated native and fusion Bt genes that had been tested in cabbages and in cotton had not been expressed at insect controlling levels. (Depos. desig. May 30, 2002 P.105 L.8-22).

Contrary to the view expressed by other Bayer officials that Bayer had limited resources and wanted to channel its attention in corn, Dr. Reynaerts has a different view as to why Bayer discontinued its work on insect control in cotton in 1991 or 1992. She said it was because "we had no U.S. partner." (Depos. desig. May 30, 2002 P.113 L.6-13). Dr. Reynaerts is very forthcoming with her testimony.

Celestina Mariani is a professor of biology at the University of Nijmegen. She appeared refreshingly truthful in her video deposition, but adversarial in her later testimony. She graduated from a university in Naples, Italy, on a thesis of Drosophila, a fruit fly. She studied post doctorate in the Netherlands for two years where she now teaches. She went from there to Germany for three years where she was employed at the European Molecular Laboratory until going to Bayer on January 1, 1985. When asked how long she worked for Bayer she first said that she is still there, until appointed in Nijmegen, "so that would make about eight years from 1985 to 1993." Her deposition was taken December 10, 2002. She testified that there was very good communication at Bayer. Scientists exchanged information, material, experience, expertise, medals and protocols. (Depo desig. Dec. 10, 2002 P.6 L.7-11; P.6 L.15-24;P.6 L.25-P.7 L.11; P.8 L.2-8;P.9 L.7-P.10 L.3).

Appendix F

In October 1985, as earlier mentioned, Dr. Mariani attended the International Society of Plant Microbiology in Savanna, Georgia, for Bayer. She was given a book of abstracts at the meeting, and while there, visited a poster presentation on Bt, believing it would be interesting for Bayer, although she had never worked on Bt. She wrote some notes to take information back to her colleagues from the poster which included the language, "[w]e have found that the second half of the Bacillus thuringiensis toxin gene is dispensable for the expression of an active insecticide." (Depo desig. Dec. 10, 2002 P.24 L.18-22). She identified the Barnes' abstract (not to be confused with her poster notes) as Plaintiff's exhibit 79. She took the Wayne Barnes' Abstract and the notes she had taken from the poster presentation back to her colleagues. She concluded the language on the last page of the abstract means the "second half of the protein, and that can be removed and still deleted protein would have insecticidal activity." She explained that the carboxyl terminus would be removed from the gene and the protein expressed would still be an active insecticide. The second half means the carboxyl side of the gene. (Depos. desig. May 30, 2002 P.24 L.23-P.25 L.5). Her description cited in conjunction with the testimony of Dr. Meulemanns, above, demonstrates the detail and scope of her notes and of her recollection of them.

When she returned to Belgium, she showed her notes to Herman Hofte and Johann Cardoon. She may have shown them to Marc Vaeck. She remembers that the author of the abstract was Wayne Barnes. She

concluded her testimony by saying, "I wish I'd never written those notes, but I really thought I was doing very good at that time, giving the information to my colleagues, but I understand it may turn against it." She was then asked, "[i]f a molecular biologist were given the DNA sequence of several Bt genes, would he be able to determine which ones had an xho restriction site?" She answered, "[v]ery easily." (Depos. desig. May 30, 2002 P.70 L.7-15). Dr. Mariani was not evasive in her deposition responses.

Stefan Jansens is employed by Bayer CropScience in Ghent, Belgium, as an entomologist. He studied at the University of Ghent studying Agricultural Engineering. His thesis was written on the subject of the effect of Bt on tropical insects. He has the United States' equivalency of a Masters Degree. His thesis was on "activity of tropical insects." After graduation, he spent ten months in the Army. He began employment with Bayer as its sole entomologist in May 1984, when Bayer had twenty-five employees. He was the only entomologist. During his first few years at Bayer, Mr. Jansens worked with Cabbage White Butterfly and Tobacco Hornworm for, which he had the responsibility of rearing. (Trial tr. Vol IV Part A P.55 L.18-24;P. 56 L.3; P. 57 L.2-21; P.58 L.8-14:P.59 L.12-P.60 L.3:p.60 L.16-18). Mr. Jansens was deposed on the 28th day of May, 2002. Designated portions of that video deposition were played in Monsanto's case in the inequitable conduct hearing, and he was presented by Bayer for live testimony.

Appendix F

At the time of his deposition, he was employed at Aventis CropScience, N.V., a company acquired at least, in part, by Bayer, as "programme leader" for Bt corn and Bt cotton. The first project Mr. Jansens worked on for Bayer was the Bt project. At first, he did not transform plants. "We . . . started different Bt proteins" and what "I also did was testing different buffers to see which is the best buffer to dissolve the different Bt proteins." (Trial tr. Vol IV Part A P.62 L.10-13). At that time, Bayer had Bt2 but it was in E. Coli, not plants. He started transforming tobacco plants in 1985. The first transformed tobacco plants Mr. Jansens tested did not kill bugs. The first time PGS discovered it had produced a plant that killed bugs was in December 1985. He had taught Veronique Gosselle how to score the insect assays so she could perform some work while Mr. Jansens was on holiday. When Mr. Jansens returned, he reviewed Ms. Gosselle's notebook and observed growth inhibition, and observed that plant 2111 showed clear mortality. (Def. Ex. No. 1153 P.36) (Trial tr. Vol IV Part A P.67 L2). Mr. Jansens testified that "[i]n the beginning we were only interested in growth inhibition, but then as soon as we found these plants with high mortality, for the new plants we tested we were only interested in the mortality." (Trial tr. Vol IV Part A P.68 L.21-24). After achieving success reflected in Defendant's exhibit 1153, to determine if plants were candidates for commercial development, Mr. Jansens testified, "[w]e looked to the plants that had high mortality and, roughly, we say that plants had to have mortality in this kind of bioassay of above 80 percent." (Trial tr. Vol IV Part A P.69 L.9-14).

Appendix `F

Dr. Cardoen asked Mr. Jansens to submit a declaration to assist Bayer in its patent application, with test results in addition to the results from bioassays he supplied when the patent was first filed. Dr. Cardoen explained to Mr. Jansens, concerning the status of the patent application before he submitted his declaration, "[h]e said that in our patent we will be limited to CryIA(b) in tobacco . . . He asked me to summarize my data of Bt plants that were not tobacco and were not CryIA(b) in tobacco." (Trial tr. Vol IV Part A P.70 L.13-23). Mr. Jansens signed the declaration on September 9, 1991. The declaration, in part, states, "**[i]n order to demonstrate that generally any truncated Bacillus thuringiensis ("Bt)" gene could be expressed in generally any plant to provide an insect controlling amount of its encoded Bt polypeptide toxin in the so-transformed plant as disclosed in this application, the following tests were carried out under my supervision; . . .**" (Def. Ex. No. 1474)." Paragraph 6 of the Jansens' declaration states, in part, "**I know of no test results which are contrary to or inconsistent with the test results set forth above in table 3 and in appended Figures 1 to 11 and Tables 1 and 2 or which would lead to different conclusions from those expressed above.**" Mr. Jansens testified that was still his belief on the final day of the hearing when live testimony was received. Mr. Jansens did not appear to be believable.

It is clear beyond question that all functions concerning genetically engineered plants at Bayer, from the earliest stages of growth of insects, raising of plants,

conducting of bioassays, testing of plants for expression of Bt toxin, development of consortiums for development of commercial products, securing of patents and efforts to expand the scope of patents, were fully integrated in the various specialty groups which met regularly and on a continuous basis. Individuals in those groups engaged in aggressive communication, all documented through frequent memorandums, reports and electronic mail. The responsibilities of these groups is detailed early in this opinion. Regular meetings of the insect control group were held beginning in 1987. These meetings were regularly attended by Dr. Peferoen, Dr. Cornelisson, Dr. Reynaerts, Mr. Jansens and Dr. Cardoen. If there were failures with respect to obtaining Bt plants, that would be discussed." (Peferoen Depos.tr. May 23, 2002. P. 25 L.16-23). Mr. Jansens confirms this practice in his own words taken from the deposition designations.

Q. Now how did you interact with the other groups, say the plant transformation groups and the Bt expression groups?

A. Well there were the regular, often meetings and then the people like Marnix Peferoen. Marc Cornelissen, Arlette Reynaerts and Bart Lambert, we met on a regular basis.

Q. What was discussed at these regular meetings?

A. All the new details for the previous periods.

Q. For each group?

A. For each group.

Q. Is it correct to say then that you would take whatever data you had recently generated and present it or describe it to the other groups involved in the Bt meeting?

A. Yes, I would present it.

Q. What role did Dr. John Cardoen play?

A. He was also present. He was responsible for patenting for the patents.

(Jansens dep. May 28, 2002 P. 20 L. 16-P.21 L.9; P.211.19-22).

Mr. Jansens testified that he had not studied the '799 patent and the last time he looked at it was "[p]robably a very long time ago." (Jansens dep. May 28, 2002 P.12 L.23). He evaluated all of the Bt plants that have been made by Bayer over the past 20 years except when he was on holiday, and he did all of the entomological bioassays. (Jansens dep. May 28, 2002 P.13 L.9-13; P.16 L.13-17). He was the person within Bayer who was most knowledgeable about insect bioassays, the

activity of the Bt plants at Bayer over the last 20 years. (Jansens dep. May 28, 2002 P.17 L.17-P.18 L.2). If an experiment concerning insecticide controlling properties of a plant was conducted, Mr. Jansens would have been the person to know about it. (Jansens dep. May 28, 2002 P.18 L.4-7). Mr. Jansens testified that Dr. Cardoen was not an attorney, but was a scientist who was an entomologist more in biochemistry and microbiology who was technically capable of understanding and summarizing the results that the Bt group had obtained.

Mr. Jansens testified that when he submitted his declaration to the United States Patent Office he understood that the declaration was being provided to the patent office for the purpose of persuading the patent office that the claim should not be limited to just tobacco or to just CryIA(b). (Jansens dep. May 28, 2002 P.172 L.24-P.173 L.14). The following questions and answers were reported in his testimony:

> Q. And you understood that when the declaration was submitted, the patent examiner in the United States would be relying upon the words that you put down in that declaration and swore were true in order to consider whether or not to allow the '799 patent?
>
> A. You mean that the patent judge would consider my data?
>
> Q. Yes.

A. Yes, I knew.

Q. Did you also know that the examiner was not in a position to go back and test your results to determine whether they were correct or incorrect?

A. No, I didn't do that.

Q. Did you know that the examiner was required to rely upon what you said to be true and complete.

A. Yes.

(Jansens dep. May 28, 2002 P.173 L.15-P.1174 L.9).

There is no question that Bayer had been denied the broad scope of its claims by the United States Patent Office, and there was a pressing need to gain the approval of the Patent Office of the claims expeditiously, because of rapid-paced developments by many competitors. Mr. Jansens was asked, "[b]ut in particular, in your group, and there are some documents we can get to later, there was pressure on your group to get patents issued in he United States and elsewhere?" He answered, "I think so, yes." The next question was, "[y]ou know there was very much pressure to get patents issued at the time?" His answer was, " [i]t's the need to protect our work." After questions about when Bayer filed for its first Bt patent and none had been issued, Mr. Jansens was asked, "[s]o there was pressure

to get it done on Bt genes, not just in general?" Mr. Jansens answered, "[y]es. We wanted to get a patent issued." (Jansens dep. May 28, 2002 P.33 L.15-22; P. 34 L.16-19). On June 11, 1991, there was a Bt meeting attended by Mr. Jansens, where it was related that an office action had been received from the United States Patent Office in connection with Bayer's Bt pending application. Dr. Cardoen states, "it appears we are back to square 1." Then he says, "[e]xaminer urges us to limit our claims to the Bt2 gene and tobacco" (Jansens dep. May 28, 2002 P.27 L.6-17) (Pl. Ex. No.683). Very significantly, this was slightly less than three months before Mr. Jansens signed the September 9, 1991 declaration.

Bayer's exhibit 1474 (deposition exhibit 50) is the Jansens' declaration, which was signed on September 9, 1991. Mr. Jansens testified that he prepared all the parts about the description of the bioassays and the results. (Jansens dep. May 28, 2002 P.28 L.13-P..29 L.12). Dr. Peferoen "probably" reviewed it and Mr. Jansens said that he "probably" talked to Dr. Cardoen about it. When asked how he knew what to put in it, Mr. Jansens testified, "I don't remember any more. Probably we talked about it." (Jansens dep. May 28, 2002 P.31 L.16-18). "We" included Mr. Jansens, Dr. Peferoen and Dr. Cardoen.

Plaintiff's exhibit 705 (deposition exhibit 59) is a summary of the January, 1992 Bt meeting in a memorandum prepared by Dr. Cardoen reflecting that, after Mr. Jansens submitted his declaration to the

Appendix F

United States Patent Office, Dr. Cardoen received notification from the Patent Office that all claims were allowed. (Jansens dep. May 28, 2002 P.175 L.3-17). Mr. Jansens was asked about his failure to report negative results in cabbage, cotton, and corn.

Q. As far as your reports to the Bt committee, there were negative results in cotton, correct?

A. We didn't find cotton plants with high mortality.

Q. Now, if you were telling the patent office the whole truth, you would have told them about the cotton plants, correct, because those were plants that you had worked on?

A. We worked on the cotton plants.

Q. But you withheld that information from the patent office, the information on the cotton plants?

A. The Bt cotton information was not in the declaration.

Q. At no other time did you ever give it to the patent office, correct, after the declaration?

Appendix F

A. The results of the Bt cotton was not given to the patent office.

Q. And if you were telling the patent office the whole truth, you would have given them the results in corn, correct?

A. The data of the Bt corn was also not given to the patent office.

Q. And the data on Bt corn was also negative, correct?

A. One of the plants showed growth inhibition and it was not further confirmed.

Q. But otherwise, negative, correct?

A. Plants that we went though in my notebooks were all negative except that one.

Q. And if you were telling the patent office the whole truth about what you knew, you would have told them that you had negative results in cabbage as well, correct?

A. The Bt cabbage work was not in the declaration.

Q. And you didn't give it to the patent office at any other time, either, did you?

A. The Bt cabbage work was not later given.

Q. Don't you believe those results, the fact that three of the crops you tested gave negative results, would have been information that would have been important to the patent office in deciding whether or not to allow this patent?

A. I'm not very knowledgeable about the patents, so for me, as an entomologist, it's hard to assess this.

Q. But, in any event, the patent office didn't get a chance to assess it because you didn't present the data, correct?

A. The data of the cabbage, cotton and corn was not presented to the patent office.

(Jansens dep. May 28, 2002 P. 230 L.17-P.232 L. 23). This testimony demonstrates that Mr. Jansens knew of negative test results which were in direct conflict with his representations to the United States Patent Office. These non-disclosed tests were highly material, and show that Mr. Jansens' declaration was false and misleading. Mr. Jansens is evasive and is not a believable witness.

Appendix F

In repeated instances, Mr. Jansens tested cabbages, cotton and corn and received negative test results for expression of Bt toxin. He did not disclose those negative test results, but in addition submitted a signed declaration, agreeing to tell the truth, saying, "I also declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of this application or any patent issuing therefrom." Mr. Jansens' lack of candor and good faith, in the Court's view, would have been significant to a reasonable patent examiner. A review of all of the information in evidence reveals by clear and convincing evidence that Mr. Jansens intentionally filed highly material false and misleading information in his declaration to the United States Patent Office with the intent to deceive or mislead the PTO examiner.

Appendix F

THE FOLLOWING INFORMATION REPRESENTS POSITIVE TEST RESULTS SUBMITTED WITH MR. JANSENS' SEPTEMBER 9, 1991 DECLARATION TO THE UNITED STATES PATENT OFFICE.

In Figure 1 CryIA(b) potato was tested against tobacco hornworm. Compared to the control there were many plants with "hundred percent mortality and the lowest was 80 percent mortality." (Trial tr. Vol IV Part A P.87 L.15-17). Figure 2 is CryIA(b) tomato and "many plants that give hundred percent mortality." (Trial tr. Vol IV Part A P.87 L.19-P.88 L.1). Figure 3 tests CryIA(b) potato against potato tuber moths. He did bioassays with leaf material and with tubers. Leaf control was "less than 20 percent . . . [a]nd you see that we find quite a lot of plants with mortality higher than 80 percent . . . and you see that we find some lines that give hundred percent mortality on the tubers." (Trial tr. Vol IV Part A P.88 L.4-24). Figure 6 tests tomato containing both proteins CryIA(b) and CryIC. "[T]he plant that we tested that contains both protein gives a hundred percent mortality." (Trial tr. Vol IV Part A P.89 L.4-16). Figure 8 tests CryIC tomato against Spodoptera littoralis resulting in "a mortality around 60 percent, and you see that there's also some growth inhibition (Trial tr. Vol IV Part A P.90 L.2-8)." Figure 9 tested CryIB tobacco with potato tuber moths. "[Y]ou see around 60 percent mortality . . . and these two plants show a clear growth inhibition." (Trial tr. Vol IV Part A P.91 L.21-P.92 L.11). Figure 10 tests CryA(a) tobacco

against Manduca sexta.[9] "[W]e found several plants that give a hundred percent mortality." (Trial tr. Vol IV Part A P.92 L.18-25). As to all of these tests, Mr. Jansens testified that he was unaware of any tests that contradicted these results summarized in these figures included in his declaration to the patent office. Mr. Jansens testified that the figures attached to the declaration were not all created specifically for the declaration. "A couple of the figures and tables already existed from previous reports." (Trial tr. Vol IV Part A P.74 L.23-P.75 L.2). In his deposition he was specifically asked "was there a new set of experiments designed and carried out for purposes of preparing this declaration or did you just go to data that already existed and compile it in this declaration?" He answered, "[t]his was detail that already existed and it was compiled." (Jansens dep. May 28, 2002 P.35 L.10-16).

Obviously, some of the results were specifically prepared for the declaration. Figures 4, 5 and 7 and Tables 1 and 2 were not especially created for this declaration. The remaining, were.

Figure 4 relates to results of CryIA(b) tomato plants. It is very apparent from the time of the giving of his deposition testimony on May 28, 2002, to the time of his trial testimony in person, Mr. Jansens tries to explain away the significance of his deposition testimony as it relates to all of the negative test results he observed in his experiments in his live testimony, by testifying that

---

9. Manduca sexta is Tobacco Hornworm.

what he really meant was he was only interested in higher than 80% mortality rates in insects and that PGS officials were only interested in **commercial levels** of insect control and **conclusive results,** to explain why he did not include obvious known negative results in his declaration. Yet, in his disclosed results in Figure 4, he says, "[a]nd you see that like at the high infestation, there's a clear reduction of number of insects per plant." (Trial tr. Vol. IV Part A p.79 L. 14-18). All of his figures and tables do not support his proposition that only 80% or greater mortality was significantly reportable.

Figure 5 is the same CryIA(b) tomato plants tested against the same insect in field trials as opposed to laboratory testing. Mr. Jansens testified, "if you compare the Bt plants to the control, you get a reduction from roughly about 50 percent damaged fruits to about 10 to 20 percent damaged fruits." (Trial tr. Vol. IV Part A P.81 L.13-16). The results did not meet the 80% threshold.

Figure 7 tests a tomato plant that expresses two Bt proteins. The CryIA(b) tomato was re-transformed with the CryIC protein and tested against Spodoptera littoralis. Mr. Jansens testified, "you get about 50 percent mortality in the — in the plants, and in the control you only get about five percent." (Trial tr. Vol. IV Part A P.82 L.6-7). The 80% level is not reached here. Figures 4, 5 and 7 were prepared from data that existed before he was asked to prepare the declaration.

In Table 1, Mr. Jansens said, "[a]nd what you see is that there is a reduction in number of damaged fruits

when you compare the Bt plants with the control plants." (Trial tr. Vol. IV Part A P.82 L.19-21).

Regarding Table 2, Mr. Jansens testified, "[a]nd we counted the number of injuries smaller than the one millimeter, between one and three millimeters and so on. And what you see is that on the Bt plants, the — especially with the largest sized injuries, that there is a reduction in these numbers" (Trial tr. Vol. IV Part A P.83 L.1-5). Table 3 was not included in Defendant's exhibit no. 1474 submitted to the Court.

The remaining tables or figures in his declaration to support broader claims were prepared specifically for inclusion in the declaration. They deal with leaf and tubor bioassays, or a test with small potato tubers.

Figure 1 included test results of CryIA(b) potato against tobacco hornworm. This is an easy bug to kill. Control mortality was zero to five percent and other plants had mortality as high as 100% to a low of 80%. (Trial tr. Vol IV Part A P.86 L.22-P.87 L.2).

Figure 2 tests CryIA(b) in tomato against the same easy to kill tobacco hornworm. He said, "many plants that give hundred percent mortality." (Trial tr. Vol. IV Part A P.87 L.19-P.88 L.1).

Figure 3 tests CryIA(b) potato against potato tuber moth with two kinds of bioassays, one with leaf material and one with bioassay with tubers. In the leaf bioassay, the leaf control was less than 20 percent compared to

mortality in the plants higher than 80 percent. With the tuber bioassay control was less than 20 percent mortality and "we find some lines that give hundred percent mortality on tubers." (Trial tr. Vol. IV Part A P.88 L6-24).

Figure 6 tests CryIA(b) and CryIC tomato against Manduca sexta. Control is zero percent mortality "and the plant that we tested," says Mr. Jansens, "that contains both protein gives a hundred percent mortality." (Trial tr. Vol. IV Part A P.89 L.4-16).

Figure 8 tests CryIC tomato against Spodoptera littoralis, and Mr. Jansens states, "[a]nd you see the control gives a very low mortality, and the plants give around — a mortality around 60 percent, and you see that there's also some growth inhibition." (Trial tr. Vol. IV Part A P.90 L.2-8). Even with the specially designed tests for inclusion in the declaration, the 80% mortality rate Mr. Jansens testifies he had to have to consider the test conclusive or at a commercial level to explain away his ignoring of negative results, is not satisfied with his own data. Mr. Jansens is not a believable witness.

Figure 9 tests CryIB tobacco with potato tuber moths. Control had less than 20 percent mortality and he said these "two events you see around 60 percent mortality. That — And if you look to the control, these are nicely grown, and these two plants show a clear growth inhibition." (Trial tr. Vol. IV Part A P.91 L.24-P.95 L.7).

Appendix F

Figure 10 tested Cry A(a) tobacco against Manduca sexta. Controls are less than 20 percent and "you see that we find several plants that give a hundred percent mortality." (Trial tr. Vol. IV Part A P.92 L. 18-25).

Mr. Jansens tries to explain away the negative test results he did not disclose to the United States Patent Office in other ways. The many reports and memoranda disprove Mr. Jansens' testimony clearly and convincingly. His position is that he did not base his opinions set forth in his September 9, 1991 declaration on internal memorandums like Plaintiff's exhibit 691, but, he testified, "I went through my notebooks and made that summary on the basis of my notebooks." (Trial tr. Vol. IV Part A P.95 L.6-11). He testified that during his deposition that he did not have his notebooks, and about ten years passed between the time he last looked at his test results on the plants described in Plaintiff's exhibit 691 and the date of his deposition. (Trial tr. Vol. IV Part A P.95 L.12-21). As explained later in more detail, he later was reminded that he was mistaken, and it was really about four years between the time he reviewed the test results and his deposition. Another of the problems for Mr. Jansens' credibility is that while he says he does not rely on the memoranda, the test results discussed in most of them were his test results, and he participated in meetings with his colleagues, which the memoranda memorialized.

In addition to negative results known to exist by Mr. Jansens at the time he signed the declaration, there were other test results of which he later learned which

also were not disclosed to the PTO Examiners. Mr. Jansens testified that he did not understand that he had any obligation to supply the United States Patent Office any information after he submitted his declaration. In any event, he claimed that between September, 1991, and the end of 1993, he had received no data that changed or was contrary to the opinions stated in his declaration. Specifically, he testified, "I had no data that contradicted my declaration." (Trial tr. Vol. IV Part A p.72 L.4). This is untruthful testimony.

Mr. Jansens was asked on direct examination about the following language in his September 9, 1991 declaration which states, **"I know of no test results which are contrary to or inconsistent with the test results set forth above in Table 3 and in appended Figures 1 to 11 and Tables 1 and 2 or which could — would lead to different conclusions from those expressed above."** He was asked, "[w]as that your belief on September 9, 1991?" Mr. Jansens answered, "[y]es, it was." He was asked, "[i]s that still your belief?" He replied, "[y]es, it's still my belief." (Trial tr. Vol. IV Part A p.74 L.8-16). This testimony is not believable.

Mr. Jansens was shown Plaintiff's exhibit 691, a memorandum written by Marnix Peferoen admittedly received by Mr. Jansens which states, in part, on page two, "[e]xpression levels were insufficient to obtain insect control in Brassicae and cotton." (Trial tr. Vol IV Part A 94 L.12-P. 95 L.4.). He acknowledges that during his deposition, he was asked about Plaintiff's exhibit 691 and was shown his notebooks containing actual results

referenced there. He was asked by Bayer's counsel in Bayer's case, "[h]ow many years had passed between the time you had last looked at your test results on these plants and the date of your deposition." He answered, "I think it was about ten years." (Trial tr. Vol IV Part A P.95 L.5-21).

After being reminded on cross-examination of his obligation under oath to tell the truth, on cross-examination he was asked, "[n]ow, in view of understanding your obligation to tell the truth in this courtroom, is there anything you want to say to me now or to correct any of your prior testimony before we go any further?" Mr. Jansens answered, "[n]o." (Trial tr. Vol IV Part B P. 26 L.12-16). Mr. Jansens was asked if earlier in his direct examination he had been asked how many years had passed "between the time you had last looked at your test results on these plants and the date of your deposition." He answered , "[i]t was about ten years." (Trial tr. Vol IV Part B P. 26 L.17-22)." When shown Plaintiff's exhibit 1199,[10] Mr. Jansens admits that he had, in fact, reviewed his test results in 1999, after having been presented his own declared language (North Carolina litigation declaration) which read, "I have reviewed the data in my notebooks, and I have

---

10. Mr. Jansens was asked to sign a declaration for Bayer explaining his September 9, 1991 declaration to the United States Patent Office, at issue in this lawsuit, in another lawsuit in North Carolina brought by PGS against Ciba-Geigy. Plaintiff's exhibit 1199 is a transmittal letter dated March 2, 1999, with the North Carolina declaration of Stefan Jansens attached on page two, dated February 26, 1999.

found the tests I conducted on the mortality and growth inhibition of insects on control, nontransferred cotton plants were too high . . . ." On page four of the exhibit, he stated on February 26, 1999, that "I have reviewed my laboratory notebooks for results on insect bioassays on Brassica . . . ." He admitted in his trial testimony before this Court that, in fact, he had reviewed his notebooks in 1999. Upon further questioning concerning examination of his notebooks on Brassica, he confesses that he had reviewed his notebooks in 1999. He was then asked, "[s]o when you made the statement in this courtroom that you hadn't reviewed the data or the laboratory notebooks for 10 years, that's not true?" Mr. Jansens answered, "[n]o. It was only about four years." (Trial tr. Vol IV Part B P.28 L.23-P29 L.4). Mr. Jansens was next asked if he had earlier testified in this case on direct examination, that if after he signed the September 9, 1991 declaration, "it never came up again until this litigation," to which question Mr. Jansens answered, "[y]es." He was asked, "[s]o that statement was not true either." Mr. Jansens answered, "[n]o." (Trial tr. Vol IV Part B P.29 L.8-19). Next, he was shown a memorandum from Dr. Meulemanns to Barbara Walker dated February 23, 1999, which states, "Stephan informed me that the cotton plant quality was very variable in those days; some plants were not normal . . ." (Pl. Ex. No.1197). In the second paragraph, there is a review stated by Dr. Reynaerts reporting that Bt cotton could be made by Monsanto at that time. (Trial tr. Vol IV Part B P.30 L.10-18). The North Carolina declaration Mr. Jansens signed was crafted by attorneys for his execution for use in the North Carolina litigation.

(Trial tr. Vol. IV Part B P.31 L.16-P.32 L.1)(Pl. Ex. 1190). In Exhibit 1190, a Bayer lawyer sent a draft copy of the North Carolina litigation declaration to Wouter Meulemanns, asking him to send it on to Mr. Jansens for his review. The draft says, "I have reviewed my laboratory notebooks for results of insect assays on Brassica plants transformed with truncated genes. Prior to September 1991, only a preliminary–and then paragraph or a bracket." Mr. Jansens was asked whether he would agree with the statements the lawyers drafted. Mr. Jansens testified, "I say they were not preliminary." (Trial tr. Vol. IV Part B P.31 L.16-32 L.24).

Finally, regarding Plaintiff's exhibit 691, in his deposition testimony, Mr. Jansens acknowledges that Dr. Peferoen prepared the report for the April 30, 1991 meeting of the insect control programme, copied to Mr. Jansens, which Mr. Jansens acknowledged he received. Dr. Reynaerts reports insecticidal levels of CryIA(b) were obtained in tobacco, tomato and potato. (Pl. Ex. No.691). Mr. Jansens was asked, "[a]nd it was also reported to you that the expression levels were insufficient to obtain insect control in brassica and cotton, correct?" He says in response, "[t]hat's what Arlette Reynaerts is stating in this document." (Jansens dep. May 28, 2002 P.98 L.12-17). He acknowledges that information was reported to him that expression levels as determined by Elisa were insufficient to obtain insect control in either Brassica or cotton, and he had that information at the time he filed his declaration with the United States Patent Office. (Jansens dep. May 28, 2002

P.99 L.11-19). He acknowledge that it was reported to him, before he made his declaration to the United States Patent Office, that there was insufficient insect control observed in potato with the truncated CryIb gene, insufficient insect control potato with the CryIIIb gene and insufficient control with the CryIc gene in cotton, and he failed to put the information in his declaration. (Jansens dep. May 28, 2002 P.100 L.16-P. 101 L. 22).

When Mr. Jansens signed the September 9, 1991 declaration, he agrees that he knew about the 1990 Monsanto Perlak paper and the results in the paper on the success with truncated (modified) Bt genes in cotton published in 1990. (Pl. Ex. No. 191) (Trial tr. Vol. IV Part B P. 45 L.9-21). He admits that Dr. Perlak concluded in 1990, that a Bt gene did not work in a plant. (Trial tr. Vol. IV Part B p.48 L.1-13). He admits that Dr. Perlak did note insect resistance in a full-length synthetic gene, not a truncated Bt gene, and that Dr. Perlak concluded he got insufficient insect-control with native genes. (Trial tr. Vol. IV Part B P.48 L.14-P.49 L. 24). Contrary to his September 9, 1991 declaration, he did know of yet another negative test result which was not reported to the examiner at the PTO.

Mr. Jansens admits that it was reported to him before he signed the September 9, 1991 declaration, that with the CryIc gene, there was insufficient insect-control in cotton, and that it was reported to him before he filed that declaration that "not every Cry gene would be able to obtain insect-control in every crop . . . ," All of this information was available to him and he failed to include

it in his declaration. (Trial tr. Vol. IV Part B P.58 L.4-18). When Monsanto's counsel suggested that Mr. Jansens did not disclose the negative results in his declaration, he testified, "[w]ell, I didn't disclose all of the negative plants." When it was suggested he did not disclose the failures, he said, "I didn't disclose the negative plants." (Trial tr. Vol. IV Part B P.59 L.19-P. 60 L.3).

Mr. Jansens admits that his negative test results on a truncated native Bt gene in Brassica, upon which he made conclusions, were not reported to the patent office. (Pl. Ex. No. 1163) (Trial tr. Vol. IV Part B P.61 L.19-22; P.69 L.8-18). He admits that the Patent Office had not been shown data as to two experiments which showed there was no expression of insect-controlling amount of Bt toxin. (Trial tr. Vol. IV Part B P.69 L.25-P.70 L. 6). Of 50 cabbage plants tested, only 3 showed growth inhibition and 47 were negative. (Trial tr. Vol. IV Part B P.71 L.16-P.72 L.5).

Mr. Jansens tested about 150 Bt cotton plants and someone at Bayer did Elisa tests on some of the transformed cotton plants, confirming that the Bt protein could not be detected. (Trial tr. Vol. IV Part B IV P.72 L.19- P.78 L.7). Mr. Jansens confesses that before September 1991, he knew that it had been reported that no Bt protein could be detected in an Elisa test on some of the transformed cotton plants. Specifically he testified, "[t]he plants that we tested were reported as that we could not find Bt within Elisa." (Trial tr. Vol. IV Part B P.78 L.18-19).

Appendix F

Plaintiff's exhibit 623 reports notes of a February 15, 1988 Bt meeting, which Mr. Jansens attended. He was asked, "[n]ow in your declaration [September 9, 1991], you said you knew of no test results that were contrary to or inconsistent with or would lead to a different conclusion of the statement of any truncated Bt2 gene, correct?" He answered, "[y]es." He was then asked "[n]ow, it was reported to you and you understood from this report that ten plants transformed with the TR2' - Bt860 neo — you recognize that as a truncated Bt gene, correct?" After answering "[y]es," he was asked what was reported about the tests. He answered, "[w]ell, what was reported by Arlette Reynaerts was that no effects were observed." (Trial tr. Vol. IV Part B P.78 L.20-P.79 L.5;P.79 L.13-19). He admits that the data was prepared by him. He was then shown his September 9, 1991 declaration (Def. Ex. no. 1474) with opposing counsel reciting the following language from the declaration, "[i]n order to demonstrate that generally any truncated Bt gene could be expressed in generally any plant to provide an insect-controlling amount of its encoded Bt polypeptide in the untransformed plant as disclosed in this application, the following tests were carried out under my supervision; in the following tests, et cetera." He was asked if he understood that the tests he selected were going to be relied on in deciding whether to issue "this patent." He confirmed that he did and he understood that the declaration was made and offered under penalty of perjury. (Trial tr. Vol. IV Part B P.80 L. 2-16). He admitted he had these test results on ten Brassica plants before September 1991; he tested a native truncated Bt gene in Brassica, and

was asked if he observed negative results. He answered, "[y]es, it states that ten plants were tested and that no effects were observed." (Pl. Ex. No. 623) (Trial tr. Vol. IV Part B P.83 L.5-9;P.84 L.1-6). As to the identity of the person who actually did the experiments, Mr. Jansens was asked if there was any doubt in his mind as to whether he did the experiments in 1988, he said, "I probably did the experiments with Brassica." (Jansens dep. May 28, 2002 P.85 L.14-15). When asked if he included these negative truncated Bt gene reports to the United States Patent Office, Mr. Jansens said, "[t]here are no Brassica results in my declaration (Jansens dep. May 28, 2002 P.85 L.18-23).

Plaintiff's exhibit 654 is a report on insects at Bayer dated April 21, 1989. Mr. Jansens had, at that time, tested 160 cotton plants with CryIA(b) and CryIA(c), and had tested the CryIA(b) gene in potato, and other Cry genes or CryIA(b)[11] in tomato, and CryIC and CryIE in Brassica. He reported to the United States Patent Office on the positive potato and tomato tests but not on the negative cotton or Brassica tests. (Trial tr. Vol. IV Part B p.84 L.7-P.85 L.5).

Mr. Jansens acknowledges that he expects he received a copy of a report of December 19, 1989, including a summary of reports on bioassays which Mr. Jansens states he would have reported. (Pl. Ex. No. 670). The last line of the report states, "no cotton

---

11. The CryIA(b) gene is Bt2. (Trial tr. Vol. IV Part B P.86 L.1).

bollworm control with engineered cotton." Marnix Peferoen, Mr. Jansens' boss made the statement, and Mr. Jansens ascribes correct reporting by Dr. Peferoen. As of December 19, 1989, on the last page of the report under "conclusion," Mr. Jansens' boss states, "[w]ith the current technology, there seems to be only a few candidates; hornworms control in tobacco, tuber moth control in potato and tomato fruitworm control in tomato." As of that time, Mr. Jansens could not remember any positive results in Bt cotton or corn plants. (Jansens dep. May 28, 2002 P.91 L.23-24)

Plaintiff's exhibit 669 reports a December 19, 1989 Bt meeting attended by Mr. Jansens discussing 15 transformed truncated cotton plants with a Bt 15 gene, known as CryIC (different than Bt2). The plants were evaluated on Elisa to detect whether there was Bt protein. This document records, "[n]o Bt 15 could be detected." Mr. Jansens testified that he knew this result before he filed his 1991 declaration. (Trial tr. Vol. IV Part B P.85 L.6-P.86 L.13). Page two of the same exhibit reports negative results in seventeen Bt15 plants for Spodoptera littoralis on May 20, 1990. It was noted that three plants were to be retested, although they were not retested. At no place does Mr. Jansens mention that the results were inconclusive. (Trial tr. Vol. IV Part B P.86 L.14-P. 87 L.10;P.87 L.25-P.88 L.5). The follow-up question was, "[y]ou did not report the negative data on these 17 cotton plants with a different truncated Bt gene, did you?" (Jansens dep. May 28, 2002 P.64 L.25-P.65 L.3). Mr. Jansens responded, "I did not report this data." (Jansens dep. May 28, 2002 P.65 L.4).

Appendix F

A May 1, 1990 Bt meeting reported test results on thirteen cotton plants conducted by Mr. Jansens on Spodoptera and Heliothis with negative results. Mr. Jansens admits,"[i]t's stated in the document, yes." (Pl. Ex. No. 676) (Trial tr. Vol. IV Part B P.90 L.5-18). In his testimony, Mr. Jansens tries unsuccessfully, in response to cross-examination questions, to diminish the impact of all of his own negative test results by saying, in some instances, the tests were inconclusive, the test results were preliminary, or the Bayer employees were looking for only high mortality in tested plants. However, in each case his testimony is patently unbelievable. He tries to convince the Court that "negative" only means that there was insufficient mortality for development of a commercial product. While the test results here were reported as negative, in many places, there is not even the suggestion of growth inhibition, an unpersuasive argument he advances in some instances to argue that negative results really do not mean negative results. In response to questions regarding these thirteen plants, when it was suggested to him that he never saw "any high mortality in any of the cotton plants," he answered, "[w]e didn't find at that moment high mortalities in all cotton plants, but we found some growth inhibition." The following question was, "Right. It's true that in the Bt, truncated Bt gene in the cotton plants, you never saw high mortality, correct?" He replied, "[n]o, not at that time." (Trial tr. Vol. Part B IV P.91 L. 23-P.92 L.4). It is undisputed that before September 9, 1991, Mr. Jansens never saw high mortality in cotton plants at any time.

Appendix F

Before he prepared his declaration to the United States Patent Office in September 1991, Mr. Jansens admits that he had in his possession a June through December 1990 planning report of experiments prepared by Dr. Reynaerts. A native truncated Bt gene in cotton under Elisa analysis, "[n]ever gave any positive signal." Mr. Jansens acknowledges, "[t]hey didn't detect any Bt protein in the callus." He was asked, "[a]nd, again, you report to your colleagues within the company that all insect assays were also negative on the cotton, correct?" He responds, "[i]t's what Arlette Reynaerts reports." When asked if he didn't say the results were preliminary or inclusive, but rather he said they were negative, Mr. Jansens continues his evasive unbelievable responses. He says, "I don't know on which statements that Arlette has based this conclusion that she draws." He was asked, "[t]he information had to come from you, correct." He answers, "[y]es." (Pl. Ex. No.677) (Trial tr. Vol. IV Part B P. 92 L.5-P.93 L.15). Mr. Jansens acknowledges that he had received the report and that he had done these tests. Dr. Reynaerts then makes a condemning conclusion about expression levels in all Cry genes. Mr. Jansens was asked,

> "[i]t was reported to you by Ms. Reynaerts in May of 1990 about different Cry genes in tobacco, correct, as far as this memo shows under item number 2. In the second full paragraph under 'tobacco,' Ms. Reynaerts states, 'from these experiments (see also cotton transformations/potato transformations) we conclude that all

different Cry genes are not well expressed into plants. It has to be evaluated (mc)[12] if the problems encountered with other Cry genes are the same or similar to what is observed with CryIA(b).' Do you see that?" (Pl. Ex. No.677).

Mr. Jansens responded, "[y]es" (Jansens dep. May 28, 2002 P.69 L.21-P70 L.10). Mr. Jansens was asked, "[y]ou selected the plants that worked, that gave positive results, correct, in your declaration?" He answered, "I summarized the data of positive plants." He was next asked, "[a]nd the only data that you summarized and the only data that you gave to the United States Patent Office were in plants that worked or gave positive results, correct." Mr. Jansens testified, "[t]he positive plants were in the declaration" (Jansens dep. May 28, 2002 P.71 L.2-12). Mr. Jansens was asked, "[b]ut anyway, it was your intention to exclude the negative results when you wrote your summary?" He answered, "[i]t was the intention to show the positive plants." (Jansens dep. May 28, 2002 P.73 L.5-9). When asked if the failures were not important, Mr. Jansens said, "I think the positive plants are the important ones." (Jansens dep. May 28, 2002 P.73 L.5-9). He was asked, "[a]nd the fact that you were unsuccessful at ever getting an insect controlling amount of a Bt protein in cotton, despite at least 34 plants, we've seen that many, you decided that wasn't relevant either?" He replied, "I cannot remember that exactly," (Jansens dep. May 28, 2002 P.73 L.25-P. 74 L.)

---

12. Marc Cornelissen.

Appendix F

Mr. Jansens is not skillful in his attempts to manipulate the truth before this Court. His misrepresentation of the written record with his continued perceptible untruthful testimony pervades his deposition testimony and his testimony personally presented. There are more examples! Mr. Jansens prepared Plaintiff's exhibit 693 which is a memorandum reporting on plant bioassays in potato. He testified in response to a question about the results, "[w]e tested seven CryIB plants, and all the results were negative." Then he was asked about the results of tests reported to his colleagues on seventeen CryIA(b) cotton plants. He said, "I report that we didn't find plants with high mortality." The next question was, "[w]hat did you say in the report, in your report?" He responds, "[i]n my report, I state that all were negative." He was asked, "[n]othing in here about high mortality, is there?" Mr. Jansens testified, "[y]es, but I meant that." In response to a follow-up question that there was nothing in the report about high mortality, Mr. Jansens said, "[n]o." (Pl. Ex. No.693) (Trial tr. Vol. IV Part B P.93 L.16-P.94 L.13). His continuous attempts to put a positive "spin" on irrefutable records, of which, in many cases, he was the architect, which reveal contrary conclusions, substantially contribute to the conclusion that Mr. Jansens is not to be believed.

Mr. Jansens is documented to have had knowledge of further negative tests before September 9, 1991. Plaintiff's Exhibit 687 is an internal note pertaining to Bt cabbages dated January 28, 1991, received by Mr. Jansens. It concerns a Bt meeting provided to

Mr. Jansens by Dr. Peferoen. Page two reports, "[s]o far, Bt cabbages were unsuccessful in the control of Lepidoptera." Mr. Jansens expects that he did the tests, and acknowledges that from 1988 to 1991, he worked on cabbages. Dr. Peferoen, his boss, concluded that Mr. Jansens' experiments were unsuccessful in controlling Lepidoptera insects. Mr. Jansens admits that in Dr. Peferoen's conclusions, "[h]e based his conclusion on the data of mine (Jansens dep. May 28, 2002 P.105 L.14-P.108 L.4)." Mr. Jansens admits, "[t]here are no Bt cabbage results in my declaration." (Jansens dep. May 28, 2002 P.110 L.7-8). He admits as to 687, "[i]t states that so far, Bt cabbages were unsuccessful in the control of lepidoptera." (Trial tr. Vol. IV Part B P.94 L.14-25).

Mr. Jansens received a copy of Plaintiff's exhibit 705 which is a record of minutes of a January 16, 1992 Bt meeting. Mr. Cardoen announces notice from the United States Patent Office with regard to the '799 patent, "all claims are allowable . . ." He was asked, "[a]nd you were successful in obtaining that allowance because of the declaration that you put into the Patent Office, correct?" He testified, "[y]es, I think it would have an effect." (Trial tr. Vol. IV Part B P.108 L.1-25). He knew before his declaration was prepared and filed that the patent examiner had rejected broad claims, and in his words, "I think we would be limited to — to CryIA(b) in tobacco." (Trial tr. Vol. IV Part B P.107 L. 22-25). As to whether he had a duty of candor to the United States Patent Office, Mr. Jansens said, "I don't know anymore," and later he said he didn't know at any time. (Trial tr. Vol. IV Part B P.109 L.18-P. 110 L. 6).

Appendix F

After all of the tests he had conducted, all of the meetings he had attended, all of the work of all of the other insect groups had been completed, all efforts had been made in the patent application process concerning the '799 patent and all of the negative results he had obtained in all of his testing of plants with truncated Bt genes, Mr. Jansens was aware of Plaintiff's exhibit 683, which reports minutes of a June 11, 1991 meeting by Mr. Cardoen, which reported,

> "[w]e received office action from the USPTO. It appears that we are back to square one. The examiner urges us to limit our claims to the Bt2 gene in tobacco. An interview with the examiner will be necessary. In my opinion, we could obtain fairly soon claims on patents containing Bt2 like genes. In order to obtain broader claims, we will have to go in–go in appeal. (This will probably take two years.) We will have to decide whether we should follow this strategy or whether we should try to obtain broader claims right away."

Mr. Jansens admits he knew of the strategy of Bayer. (Pl. Ex.683)(Trial tr. Vol. IV Part B P.110 L.12-P.111 L.12). The following questions and answers are reported:

> Q. And you made the choice of trying to obtain broader claims right away, correct?

A. Well, I think John Cardoen and the lawyers decided that, yes.

Q. And they came to you in order too accomplish that, correct?

A. They asked me to make a summary of my conclusive results that supports that Bt works in other crops than CryI(Ab) in tobacco.

Q. They asked you to give data that would support the — to somehow prove to the United States Patent Office that any truncated Bt gene generally would work in any plants; isn't that what they did? \

A. Johan asked me to make that summary, yes.

Less than three months later, with no new breakthrough technological developments at Bayer, nothing but the submission of Mr. Jansens' September 9, 1991 declaration to the United States Patent Office, the coveted broader claims were allowed. Mr. Jansens knowingly failed to include in his declaration test results which clearly and convincingly showed that he could not demonstrate "that generally any truncated Bt gene could be expressed in generally any plant to provide an insect controlling amount of its encoded Bt polypeptide toxin in the so-transformed plant as disclosed in this application," and more significantly, there is clear and convincing evidence contrary to his declaration "I know

of no test results which are contrary to or inconsistent with the test results set forth above in table 3 and in appended Figures 1 to 11 and Tables 1 and 2 or which would lead to different conclusions from those expressed above." This Court finds by clear and convincing evidence, Stefan Jansens did know of numerous tests carried out directly by him or under his supervision which were contrary to or inconsistent with the test results he disclosed, which would and did lead to different conclusions to the test results disclosed. The Court finds by clear and convincing evidence that Stefan Jansens knowingly made false and misleading highly material statements to the United States Patent Office, with the specific intent to deceive and mislead the PTO Examiner, in direct violation of his duty to the United States Patent Office and in violation of his sworn oath.

However, the responsibility for the unenforceability of the patents in this case caused by inequitable conduct does not lie exclusively with Mr. Jansens. In this small undercapitalized company[13], when faced with the reality that rapid advancements were being made by Monsanto and other companies, and based on all of the truthful data that had been submitted to the United States Patent Office before the Jansens' declaration, Bayer officials knew they had very limited patentable technology based on the PTO rejections of desired broader claims. However, officials and employees of the company made the decision to press ahead to get broader claims, with reliance on known false and

13. Reference here is to PGS, now Bayer.

misleading highly material information. These conclusions are based on all of the testimony of Bayer officials and agents set forth in this opinion, not just the testimony of Mr. Jansens. Bayer had limited early success in Bt plant transformation. Rather than following the rules of candor and good faith, Bayer officials, employees and agents elected to pursue the path of dishonesty, in attempts to deprive others, with legitimate patent claims, of their rightful ownership interests.

Furthermore, Mr. Jansens attempted to deceive this Court when he submitted a declaration with Bayer's submission in opposition to a summary judgment motion of Monsanto. (Pl. Ex. No.1471). At page 6, paragraph 20, Mr. Jansens declares, "[i]n 1991, I knew that insecticidal amounts of a truncated Bt protein were expressed in cotton from the work of scientists at Monsanto published in the scientific journal *Biotechnology*." See Exhibit 5. During the inequitable conduct hearing, he was asked, "[i]f you turn to Exhibit 5, that is in fact the Perlak article which is plaintiff's Exhibit 191, correct?" Mr. Jansens confirms that with a "yes" answer. (Trial tr. Vol. IV Part B P.132 L. 19-25). Mr. Jansens confesses that his statement to this court in his declaration that he knew insecticidal amounts of a truncated Bt protein were expressed in cotton came from the Perlak article. Mr. Jansens concedes that Mr. Perlak concluded on page 1 in his article that "expression of the wild-type gene in cotton was insufficient to control insects relatively sensitive to BtK, such as cabbage looper (unpublished results)." Mr. Jansens also

confesses that the Perlak article on page 1 contradicts his declaration to this Court, but he says that in making his declaration to this Court, he was relying on page 2 of the Perlak article. (Trial tr. Vol. IV Part B P133 L. 5-P.134 L.17). Mr. Jansens was then asked, " [t]his statement contradicts the representation that you made to this court that this document shows insecticidal amounts of a truncated Bt protein were expressed in cotton, correct?" Then he was asked, "[y]our statement to the Court could not have been based on the first page of Exhibit 191, correct?" He answered, "[y]es." Mr. Jansens then says he based his statement on notes on page 2. Page 2 states, "[c]otton plants containing the wild type CryIA(b) insect-control protein gene pMon9921 showed no consistent reduction in insect damage, and lacked immunologically detectable BtK insect control protein." Some intervening questions and answers were made. He was asked, "[a]nd what you were relying upon for that statement was a sentence that says, 'The cotton plants containing the truncated Bt protein lacked immunologically detectable insect-control protein,' correct?" Mr. Jansens answered, "[y]es." (Trial tr. Vol. IV Part B P.133 L.23-P.134 L.1; P.134 L.18-P.135 L.3; P.135 L.15-19). These questions and answers followed:

> Q. And the statement to the court is about the protein being out of the plants, correct?
>
> A. My statement is about insect-control.

Q. Your statement is about insecticidal amounts, correct?

A. Yes.

Q. Of a truncated Bt protein, correct?

A. Yes.

Q. And you had in front of you the statement by Dr. Perlak that they saw no Bt protein detected in those tests, correct?

A. They stated they lacked immunologically detectable BtK insect control protein.

(Trial tr. Vol. IV Part B P.135 L.16-P.136 L.10).

In paragraph 21 of his declaration to this Court, Mr. Jansens declares that in addition to the *Biotechnology* journal, he was aware of a presentation at a Beltwide Cotton Conference in January, 1990, concerning a talk by Toni Armstrong of Monsanto indicating complete control of Trichoplusia in cotton was observed. Dr. Reynaerts prepared notes of this conference and Ms. Armstrong's talk, and Mr. Jansens admits there is no reference in the notes as to whether the Bt gene was a truncated gene or a full-length gene. The following questions were asked and answers were given:

Q. So — but you did submit a declaration, under penalty of perjury to this court, relying upon this information, correct?

A. Yes.

Q. And representing to this court that this information supports that opinion, correct?

A. Yes.

Q. Now, and you didn't have any information at all that there was a truncated gene in these cotton plants, did you?

A. I think at that moment we knew that they were also working with truncated Bt genes.

Q. Based on what, Mr. Jansens?

A. We knew that.

Q. Based on what did you know that?

A. I don't know that anymore.

Q. So in this affidavit that you presented to the court to overcome summary judgment, the documents that you relied upon just did not support the opinions that you were advancing to this court?

Appendix F

A. *No.*

(Trial tr. Vol. IV Part B P.136 L.11-P.137 L.2;.138 L.9-P.139 L.2).

It is the opinion of this Court that Stefan Jensens is not circumscribed by the bounds of truth in giving testimony, but rather appears here by deposition and in person, as a stringed-puppet, armed to say anything to advance the cause of his Company, irrespective of the harm intended to be caused to patent applicants who abide by the rules of the United States Patent Office. Clearly and convincingly, the Court finds Bayer did not subscribe to the rules of candor and good faith with the PTO, but knowingly provided false and misleading information to the PTO with the specific intent of deceiving or misleading the PTO examiner to gain broad claims which their research and tests did not support.

Joachim Messing, Ph.D, a professor of Molecular Biology at Rutgers University, is an expert witness for Monsanto. He has maintained an interest in the regulation of gene expression in plants since 1978. In particular, he has studied gene expression in seed, investigating how it might affect the nutritional quality of corn. He was nationally recognized as a member of a group that sequenced the rice genome. He is a member

of various boards of journals and former editor of Gene Magazine.

Dr. Messing reviewed the '799 file history, observing that PGS was pursing claims for chimeric genes that would express the Bt toxin protein in plants unlimited to any particular plant species or any type of Bt gene, other than a size limitation of 60 to 80 kilodltons. He noted that the United States Patent Office examiner had earlier rejected Bayer's claims, concluding that Bt genes in plants were in a state of unpredictability. After reviewing Joint Trial exhibit 6, page 501, the examiner, in rejecting Bayer claims, stated, "[s]pecifically, the disclosure is enabling only for claims limited in accordance with the teachings of the specification with regards to the Bt2, Bacillus thurngiensis Berliner, 1715 crystal protein gene, where the insecticide encoding fragment found in any of . . ." — then she lists a number of constructs. Dr. Messing states that the examiner's reason for the rejection was "[e]xpression of a bacterial gene, especially in Bt toxins, in a plant cell is highly unpredictable as shown by Vaeck, et.al., Fischhoff, et. al., and Barton, et. al." (Trial tr. Vol. II Part A P.9 L.2-P.11 L.2). To overcome this rejection, Dr. Messing testified, Bayer submitted the Jansens' declaration which stated, in part,"[i]n order to demonstrate that generally any truncated Bacillus thuringiensis Bt gene could be expressed in generally any plant to provide an insect-controlling amount of its encoded Bt polypeptide

toxin in the so transformed plant as disclosed in this application, the following tests were carried out." (Def. Ex. No. 1474) (Trial tr. Vol. II Part A P.13 L.8-13). Mr. Jansens had performed tests on tobacco, tomato and potato. He observed that Mr. Jansens had stated further in his declaration, "[t]he test results shown in appended Figs. 1 through 11 demonstrate that any truncated Bt gene can generally be used to provide an insect-controlling amount of the encoded Bt polypeptide toxin in generally any plant transformed with the truncated Bt gene." Mr. Jansens also concluded in his declaration, "I know of no test results which are contrary to or inconsistent with the test results set forth above in Table 3 and in appended Figure 1 through 11 and Tables 1 and 2 or which would lead to different conclusions from those expressed above." (Trial tr. Vol. II Part A p.15 L.6-10).

Dr. Messing's testimony focused on a number of Bayer's reports. The reports, tests, test results and his comments appear below.

Appendix F

Exhibit	Tests	Results and Conclusions
1). Pl. Ex. 645 – Bt cotton report – October, 1988-January, 1989. (Trial tr. Vol II Part A P.19 L14-22).	1). Plants were tested for expression of the Bt2 gene using ELISA assay. (Trial tr. Vol II Part A P.20 L.24-P.21 L.4)	1). No detection of the Bt2 product in the extracts. Dr. Messing concluded, "if you don't make any protein, there is no use to carry out an insect bioassay." (Trial tr. Vol. II Part A P. 21 L.11-P.22 L.4)
2). Pl. Ex. 669 – Bt meeting on December 19, 1989, on cotton. (Trial tr. Vol II Part A P. 23 L.5-6)	2). ELISA tests conducted on cotton plants with Bt15 gene. (Trial tr. Vol II Part A P. 23 L.14-16).	2). "No. Bt could be detected." (Trial tr. Vol. II Part A p.23 L. 21).

Exhibit	Tests	Results and Conclusions
3). Pl. Ex. 677 – Bt Planning Report – June 1990-December 1990. (Trial tr. Vol II Part A P.24 L.21-24)	3). Transformation experiments with CryIA(b) – constructs with truncated Bt gene. ELISA tests were conducted (Trial tr. Vol II Part A P.25 L.4-11).	3). All tests were negative and all insect assays were negative. (Trial tr. Vol II Part A P.25 L.10-11).
4.) Pl. Ex. 710 – April, 1992 Corn Task Force Meeting Summary. (Submitted for significance of failing to report to PTO later discovered information on the '799 patent and its relevance to prosecution of the '565 patent). (Trial tr. Vol II Part A P.25 L. 16-21).	4). 50 transformed corn plants with CryIA(b) gene with 35s promoter, tested for European Corn Borer. (Trial tr. Vol II Part A P.27 L.8-11).	4). "Turned out to be negative." (Trial tr. Vol II Part A P.27 L.5-14).

Appendix F

Dr. Messing notes that the April 1992 report, in addition to identifying an intact gene in corn plants that tested negative in the bioassays, the transcripts were too short to give gene expression. "No full length mRNA was produced." (Trial tr. Vol II Part A P.29 L.3-14).

In 1999, as referenced earlier, during the North Carolina litigation, Bayer conducted its investigation of the cotton, cabbage and corn data reflected or not reflected in the September 9, 1991 Jansens' declaration. Plaintiff's exhibit 1189 is a letter from Jan Desomer to Eric Weisblatt with copies to Barbara Walker and Wouter Meulemans. (Trial tr. Vol II Part A P.30 L.24-P.31 L.2). Mr. Weisblatt, an attorney for Bayer states, "I went and looked at it, and I had people look at it to see if there's a problem with the [Jansens] declaration. (Trial tr. Vol II Part A P. 34 L.6-7). Jan Desomer is the person who looked into the matter and is reporting. Mr. Desomer references documents reviewed by Dr. Messing. Under paragraph C, Mr. Desomer reports as to insecticidal effects observed in cotton and Brassicae plants at PGS prior to 1991. He says, "[i]n general it seems, indeed, that almost no insecticidal effect was found for Bt cotton — Bts in cotton and Brassicae prior to September of 1991. I have no idea on the number of transgenic lines generated." (Trial tr. Vol. II Part A P.35 L.14-P.39 L.19).

Dr. Messing reviewed a 2002 declaration (Plaintiff's exhibit 1471) by Mr. Jansens purporting to explain why he did not put cotton, cabbage and corn in the September 9, 1991 declaration. Dr. Messing reviewed

Mr. Jansens' laboratory notebooks. He was asked, "[n]ow have you seen in your review of the bioassays done — the documents reporting the bioassays done at PGS anyone reporting that these bioassays that Mr. Jansens did show insect control?" Dr. Messing answered, "[n]o, I have not." (Trial tr. Vol. II Part A p.46 L. 21-25). In exhibit 1471, paragraph 20, Mr. Jansens states that he saw that someone had gotten insecticidal control with a truncated gene in cotton. Dr. Messing explains that this was not work by Bayer, but by Dr. Perlak at Monsanto. In cotton plants that reported positive results, there was a codon modified Bt gene — a synthetic gene. Results obtained with native genes, those experimented by Mr. Jansens, according to the article relied on by Mr. Jansens, at page 940, says, "[c]otton plants containing the wild type CryI(a)(b) insect controlling protein gene, pMON 9921, showed no consistent production in insect damage, and lacked immunologically detectable" — that's by ELISA — "Bt insect control protein." Dr. Messing concluded that "in their experience [from the article], the native gene is not effective." Dr. Messing was asked, "[s]o to what extent would the Perlak paper support or not support the conclusion that generally any truncated gene — any truncated gene could be expressed at insect controlling amounts in cotton?" He answered, "[i]t definitely says not any gene because the synthetic gene worked but not the native gene." (Trial tr. Vol. II Part A p.48 L. 8-23).

At paragraph 30 of Mr. Jansens 2002 declaration (Plaintiff's exhibit 1471), he states that he did not have

enough cotton plants or cabbage plants from which to draw conclusions. Dr. Messing reviewed Mr. Jansens' laboratory notebooks to ascertain the number of cotton, cabbage and corn plants he tested. Dr. Messing recorded his findings on Plaintiff's exhibit 461. One hundred seventy cotton plants were tested from over 40 different transformation events. Dr. Messing concludes that using agrobacterium transformation which was used at that time, "[t]hese were plenty enough transformation events to have successful thansformation events that express, yes." (Trial tr. Vol. II Part A p.50 L. 10-15). In cabbage, Mr. Jansens tested over 50 plants from 38 different transformation events, and Dr. Messing concluded that would be enough plants to draw conclusions as to the functioning of the Bt gene in cabbage plants.

The testimony of Mr. Jansens, relating to the attribution of growth inhibition in insects, as a means of concluding there was insect control in some of his tests, was not believable to this Court. To the contrary, Dr. Messing's testimony was believable. Dr. Messing explained that "background" means that if there is a plant with no transgene and there is associated high mortality, that is background. For example, he identifies from Plaintiff's exhibit 1471 control plant with mortality of 22-23%, which "should be zero really." "If you look at the transgenic line T15-01, it has much less mortality. It should be the other way around." (Trial tr. Vol. II Part A p.42 L. 15-P.43 L.6). He explains that some of the Bayer lines have "hundred percent mortality." Dr. Messing observed in Mr. Jansens' notebooks there was growth inhibition observed. Dr. Messing found some growth

inhibition in the controls, also, "[s]o apparently, you can get growth inhibition even if there is no protein made, but it's not due to the transgenic product." Dr. Messing was next asked, "[n]ow from all of these tests on the 170 cotton plants and the over 50 cabbage plants, did anyone at PGS ever write down the conclusion that insect control was observed?" He replied, "I didn't find any evidence for that." (Trial tr. Vol. II Part A p.52 L.1-11). The next question posited to Dr. Messing was, "[a]nd were these results that were observed by Mr. Jansens on cotton and cabbage at PGS, as reflected in the documents and deposition testimony, consistent or inconsistent in your opinion with the statements made in Mr. Jansens' declaration to the Patent Office?" He replied, "[v]ery inconsistent because they were negative." (Trial tr. Vol. II Part A p.52 L.14-19).

Dr. Messing was cross-examined by the presentation of testimony from Dr. Fischhoff who testified in the earlier trial for Monsanto. Dr. Fishhoff had been asked, "[a]nd was it uncommon in your experience, Dr. Fischhoff, that some of the plants didn't work when you made them?" Dr. Fischoff answered, "[y]es, very common." (Trial tr. Vol. II Part B. P.7 L. 16-19). He had earlier testified that some of the plants didn't work when he made them. He had testified, "[f]or some plants, even plants that we knew had taken up the DNA, to not work in terms of expressing the genes that we knew they had in them." (Trial tr. Vol. II Part B. P.7 L. 1-3). Dr. Messing was asked, "[n]ow, do you have any testimony or information that's contrary to what Dr. Fischhoff testified here?" Dr. Messing replied, "[n]o." (Trial tr. Vol. II Part B. p.7 L. 24-P.8 L.1).

Appendix F

Dr. Messing was asked on cross-examination about reported growth inhibition in insects reported in conjunction with the Desomer letter. He was asked, "[s]o again, that suggests that there is some activity by the Bt, correct?" Dr. Messing answered, "[a]gain, as I said earlier, you know, these marginal activities like growth inhibition were not really reflecting that there is expression of the Bt gene." He was then asked, "[h]ow do you know that, sir?" Dr. Messing replied, "[b]ecause of the ELISA test." The next question was, "[a]nd this actually the ELISA test is the whole foundation for your testimony about Dr. — I'm sorry, Stefan Jansens' test reports and his results, that's your ultimate backup is the ELISA test, correct?" Dr. Messing then said it was a combination "of the ELISA test to measure expression and the insect bioassays." The next question was, "[a]nd but you're saying that even when Stefan Jansens in Brassica and in cotton saw what he said was growth inhibition, you're saying that's not real because the ELISA tests were to the contrary, right?" Dr. Messing answered, "[t]hat's what I said." (Trial tr. Vol. II Part B P.31 L.8-P.32 L.2). Dr. Messing was later shown Defendant's exhibit 1548, an exhibit not disclosed on Defendant's exhibit list. The Exhibit is a publication by Dr. Fuchs, Dr. Fischhoff and Dr. Perlak of Monsanto, concerning detection of Bt. Dr. Messing was directed to page 106 then to page 111 referencing Figure 7. He was asked, "[t]his Figure 7 shows that you can get insect bioactivity; that is, some harm, some control to an insect even though there is not enough Bt being expressed to be picked up either by ELISA or by the western test, correct?" He answered, "[t]hat's what this figure

indicates." (Trial tr. Vol. II Part B P.41 L.2-6). On re-direct examination, Dr. Messing noted that Figure 7 refers to the tobacco hornworm which is very sensitive to Bt. He saw that on page 107 of Exhibit 1548, "[t]he Tobacco budworm was 44 less sensitive than the most sensitive insect, Manducta sexta, which is tobacco hornworm." He was questioned, "[s]o if you were doing this test with a different insect, then the ELISA would be more sensitive than the bioassay?" He replied, "[t]hat's correct." (Trial tr. Vol. II Part B P.52 L.11-23). Then, the following questions and answers are reported.

Q. Now, can we go to Exhibit 691. And could we go to the second — is this — this is the April and May 1991 summary which Dr. Reynaerts talked about. If we could go to the second page of this talking about the CryIA(b) test. Could we blow up down from there to just above general observations. With respect to cotton, what were they doing the bioassays with?

A. Using heliothis virescens.

Q. Were the using tobacco hornworms?

A. No, Manducta sexta was used with the nitrates.

Q. Okay. So the notion from PTX-1548 that you could have more sensitivity with tobacco hornworms, to what extent does

that pertain to the bioassays that they were doing in cotton?

A. That doesn't apply. (Trial tr. Vol. II Part A P. 52 L. 34-P.53. L.12). Dr. Messing said the same answer would apply to Brassica. (L.14).

On cross-examination, Dr. Messing was questioned about references to the need to have several thousand plants to achieve reliable test results. On re-direct, he was shown page 404 from a notebook where Dr. Armstrong was talking about 2,000 "explants." Dr. Messing explained that that does not mean 2,000 plants, but 2,000 embryos. On the other hand, reference to "20 independent transformants" does refer to 20 plants. "So would you interpret Dr. Armstrong to be saying the goal is in order to figure out if genes are working, we just need to get 20 plants?" Dr. Messing answered, "20 transgenic plants, yes" (Trial tr. Vol. II Part B P.47 L. 15-P.48 L.9).

On re-direct examination, Dr. Messing was again shown Plaintiff's exhibit 248 and the following questions were asked.

Q. Is there anywhere in this abstract where anyone at Monsanto said that any gene can work in any plant?

A. No.

Appendix F

Q. Is there anywhere where they said any gene can work in any plant and we know of no data to the contrary?

A. No.

Q. And is that what Mr. Jansens said?

A. Yes.

Q. And in your review of the data and the deposition testimony, did Mr. Jansens have data to the contrary?

A. Yes, he did.

Mr. John T. Goolkasian joined the United States Patent Office in 1964, as a junior examiner in the field of polymer chemistry and the use of polymers in laminating. He moved to supervisory primary examiner in 1969, which authorized him to make final rejections, to allow claims, allow applications and have a lot more authority than a regular examiner. He graduated from Northwestern University with a degree in Chemical engineering in 1956. He was awarded a law degree from Georgetown University in 1969. (Trial tr. Vol. III Part A P.29 L. 6-P.30 L. 15). He then became employed in a Washington D.C. law firm for five years, then returned to the United States Patent Office in 1978 where he soon went into a "special group called the Protest and Inter Parties Examiners." (Trial tr. Vol. III Part A P.32 L.2-6). That group was established to deal with allegations of

inequitable conduct. He was then promoted to the Board of Patent Appeals and Interferences which handles appeals from the examiner's final rejections. About 30 to 40 percent of his work was biotechnology. His view of 37 C.F.R. 1.56, the rule that imposes a duty of candor and good faith on patent applicants, is that it is like the *Miranda and Escobedo* rules. He refers to the case of *In re Marzocchi*, 456 F.2d 790 (1972) for the proposition that an examiner must believe what's in the specification from the viewpoint of enablement. Even if the examiner disagrees with the conclusions reached in the submitted declaration, under the case of *In re Zeidler*, 682 F.2d 961 (Fed. Cir. 1982), Mr. Goolkasian believes that the examiner still must "give way to the declaration and he must accept the conclusions reached in the declaration." (Trial tr. Vol. III Part A P.39 L. 1-12).

Mr. Goolkasian testified that when Mr. Jansens submitted his declaration in this case, the examiner "has to accept it as true." (Trial tr. Vol. III Part A P.39 L.16). Mr. Goolkasian testified that under the rules pertaining to the duty of candor and good faith, when dealing with the Patent Office,

> "from an examiner's viewpoint, he expects the attorney to tell him the truth every time; that is, if there are two ways of looking at something, he expects the attorney will tell him there's two ways to look at it and he should look at it the way the attorney believes, and that's it, but he will expect that the attorney

> will tell him the other way of looking at it. That is what candor is." (Trial tr. Vol. III Part A P.39 L.23-P.40 L.4).

He believes "if something doesn't work on corn, then you expect them to tell you it doesn't work on corn." When "[e]verybody knew it didn't work on corn," he said, "to me, that's a lack of candor," and he also added, "[a]nd good faith, yes." (Trial tr. Vol. III Part A P.40 L.5-13). He said the obligation of candor and good faith under the rule extends to '[t]he people who have this obligation are the inventors, the people prosecuting the application, and anyone who's considered to be substantially involved in prosecuting the application, and that would include the — the foreign liaison people who are actually directing the prosecution, and I've seen it include people who — like heads of corporate departments who actually are telling people, 'get me a patent on something.'" (Trial tr. Vol. III Part A P.40- L. 18-25). After hearing a recitation from 37 C.F.R. 1.56(c), Mr. Goolkasian testified that Mr. Jansens was most definitely "substantially involved" in the prosecution of the '799 patent and that the duty of candor and good faith applied to him. (Trial tr. Vol. III Part A P.41 L. 20-25).

After it was suggested to Mr. Goolkasian that Rule 1.56 contained a requirement for disclosure of "material information," he said material information is information that is "noncumulative" and information that "by itself or in consideration with other references a *prima facie* case of unpatentability, or it traverses or it cuts against

an argument that's made in favor of patentability or an argument used to assert a position of patentability." (Trial tr. Vol. III Part A P.43 L.2-9). Mr. Goolkasian testified that information does not need to be invalidating to be material. He says that the Office expects the information be brought in and tell them about it, and then you can make your arguments. (Trial tr. Vol. III Part A P.43 L. 10-20). Mr. Goolkasian described the doctrine of prima facie unpatentability. He said the examiner does a *Graham v. John Deere*[14] examination. The examiner looks at prior art and then the differences between what's claimed and what's being claimed, "or the differences, you might say, would have been obvious to one of ordinary skill in the art, and in order to do that, he always has to have a suggestion to do or a sound scientific reason to do what the applicant has done" (Trial tr. Vol. III Part A P.44 L. 8-15). Mr. Goolkasian says the examiner reads the claim as broadly as reasonably possible. A U.S. Patent is presumed to be enabling. Prior art "has to be enabling prior art, but it has to be on the subject matter, and it has to meet the statute under 35 U.S.C . § 102." (Trial tr. Vol. III Part A P.45 L. 1-3). The examiner, generally speaking, gives prior art the benefit of the doubt. In the context of Rule 1.56, "you have to look at whether or not it establishes a prima facie case of unpatentability." He testified that under a preponderance of the evidence standard, the examiner decides if prior art required to be disclosed would establish a prima facie case of unpatentability.

---

14. 383 U.S. 1, 86 S.Ct. 684 (1966).

Appendix F

Mr. Goolkasian testified that the duty of candor and good faith continues to apply to a person substantially involved in the prosecution until the patent issues, "because information crops up, and the patent office doesn't want to grant patents that are unpatentable." (Trial tr. Vol. III Part A P.53 L. 16-17). He says that until a patent issues, it is under the Patent Office control. He concludes that Mr. Jansens had a continuing obligation to disclose to the Patent Office information he knew was inconsistent with or refuted his declaration.

The prosecution history of Patent '799 was examined by Dr. Goolkasian. At pages 393-395, the examiner rejected the claims finding they were enabling only for claims limited in accordance with the "teachings of the specification with regard to the Bt2 crystal protein polypeptide toxin of B. thuringensis strain berliner 1715." (Trial tr. Vol. III Part A P.55 L.10-15). The examiner rejected the claims under section 112 for lack of enablement for not being commensurate in scope with the subject matter enabled by the specification. The examiner found that "undue experimentation would be required of one of ordinary skill in the art to practice the invention as so broadly claimed." (Trial tr. Vol. III Part A P.56 L. 7-10). She, [the examiner], limited the gene to what works. At page 429, after a traverse, the examiner was still rejecting the claims for the same reason because of "considerable uncertainty that the Bt subspecies, other Bt subspecies will express in transformed plants, and she cites DeGreve et.al. which lists 10 factors which contribute to unpredictability of expression of foreign genes generally in non — of non

plant origin in transformed plants, and so she's relying on DeGreve to give her technical support for the rejection." (Trial tr. Vol. III Part A P.59 L.6-17). Essentially, the examiner limited Bayer to the Bt2 gene alone because of the examiner's concern that the claims covered all Bt genes in all plants, Mr. Goolkasian concluded. Bayer then traverses that it is entitled to claims to any Bt gene in any plant. At page 496, once again, the examiner limits the claims to Bt2 Bacillus thuringiensis berliner 1715 crystal protein gene for her third rejection.

Mr. Goolkasian identifies page 512 as a new application with the Jansens' declaration. It was received September 26, 1991. It was a declaration under 37 C.F.R. 1.132, "usually designed to show patentability to — most times, it's used to show superior results for the product, or — or it could be shown — used to show the examiner that his position is wrong . . . ." (Trial tr. Vol. III Part A P.65 L. 14-17). He testified that usually the declaration has some form of hard evidence and is given considerable weight. Bayer's counsel then argues that the genes are truncated, and that Jansens' declaration "clearly establishes the benefits generally of truncating such Bt genes so that they are expressed in plants in insect-controlling amounts. Hence, it is respectfully submitted that applicants' claims covering any truncated Bt crystal protein encoding gene are supported by an enabling disclosure." (Trial tr. Vol. III Part A P. 68 L. 12-17). Mr. Goolkasian opined that the Jansens' declaration was submitted to the examiner as evidence that the examiner was wrong — to traverse

the examiner's rejection. The Jansens' declaration states, in part, "[i]n order to demonstrate that generally any truncated Bacillus thuringiensis Bt gene could be expressed in generally any plant to provide an insect-controlling amount of its encoded Bt polypeptide toxin in the so transformed plant as disclosed in this application, the following tests were carried out under my direction . . ." Mr. Goolkasian was asked the extent to which the examiner would be required to believe that statement to be true. He replied, "[t]he examiner would believe that. He would be required to and would believe it." (Trial tr. Vol. III Part A P.69 L. 15-16).

Mr. Jansens states at page 536 of Joint Trial exhibit 6, "[t]he test results shown in appended Figs. 1 through 11 demonstrate that any truncated Bt gene can generally be used to provide an insect-controlling amount of the encoded Bt polypeptide toxin in generally any plant transformed with the truncated Bt gene." When asked how the examiner would be required to take the statement as true, Mr. Goolkasian said, "[t]he examiner would take that statement as being true and would look at the evidence submitted and would make a decision based on that." (Trial tr. Vol. III Part A P.70 L. 4-6).

At page 6 of the Jansens' declaration, page 636 of Joint trial exhibit 6, Mr. Jansens declares, "I know of no test results which are contrary to or inconsistent with the test results set forth above in Table 3 and in appended Figure 1 through 11 and Tables 1 and 2 or which would lead to different conclusions from those

expressed above." (Trial tr. Vol. III Part A P.70 L. 12-16). He was asked, "[t]o what extent did the Patent Office examiner have to accept that statement as true? Mr. Goolkasian responded, "[t]he examiner accepts it. He has to accept it as true because he's stated it in a declaration, and it's just evidence that's in there, in the record." (Trial tr. Vol. III Part A p.70 L. 16-20). When asked if it was important for a reasonable examiner to know of test results contrary to or inconsistent with or would lead to different conclusions, Mr. Goolkasian concluded, "[y]es, very important. The Patent Office would expect that those results would be submitted." (Trial tr. Vol. III Part A P.71 L. 7-8). He was asked if the information withheld from the examiner would, in his oopinion, have been material. He said, "most definitely, it would have. Unquestionable in my mind." (Trial tr. Vol. III Part A P.72 L. 18-22).

The Jansens' declaration was filed September 26, 1991, and the '799 Patent issued in October, 1993. Mr. Goolkasian testified that Mr. Jansens had an ongoing obligation to the United States Patent Office. He said, "[t]he Patent Office says this is a continuing obligation, and they really mean that." (Trial tr. Vol. III Part A P.74 L. 13-14). He was questioned in reference to Rule 1.56(e) which states, in part, "[i]n any continuation-in-part application, the duty under the section includes the duty to disclose to the office all information known to the person to be material to patentability." Mr. Goolkasian answered, "[i]t's — what it says. It supports my opinion. It is a continuing duty." (Trial tr. Vol. III Part A P.74 L. 16-22).

Appendix F

Joint Trial exhibit 2 is the '565 Patent. Dr. Meulemanns oversaw and prosecuted the '565 Patent. Mr. Goolkasian said, "[i]t's a continuation of a division of an application which it goes into the '799 patent we just discussed." Page 965 of Joint Trial exhibit 7, the prosecution history of the '565 Patent, is an office action of March 28, 1994 concluding that at that point, all claims were rejected. Page 967 is a similar rejection which says, "[t]he claims recite a Bt insecticidal crystal protein, and applicants have not enabled the claimed invention for all Bt crystal proteins." Mr. Goolkasian concludes that these rejections were similar to the rejections in the '799 Patent. (Trial tr. Vol. III Part A P.75 L.11-P.76 L.14). The same examiner in both the '799 Patent and the '565 Patent makes virtually the same rejection in the '565 patent history as she does in the '799 patent history. In her rejection action in the '565 patent prosecution,

> "she is saying that the claims recite a first DNA fragment that encodes an N-terminal fragment of approximately 60 to 80 kilodaltons derived from DNA encoding a Bacillus thuringiensis insecticidal crystal protein, and she says, 'However, applicants have shown only B. Thuringiensis derived from the sequence shown in Figure 13. Expression of a procryotic gene in a plant cell is known to be unpredictable for the reasons enumerated in DeGreve, et.al.,' and she says that further expression of Bt toxin genes in a plant cell is highly unpredictable, as shown by Vaeck and

> Barton, and she says, 'It's concluded that it is not predictable which length fragments will be effective to provide insecticidal activity. In view of this unpredictability, it does not appear that any Bt toxin would be effective in any plant cell against any species of insect. Consequently, applicants' broader claims are not enabled.'" (Trial tr. Vol. III Part A P.76 L.18-P.77 L.12).

Regarding the '565 patent at page 970 of the prosecution history, in the March 28, 1994 office action, the examiner also rejected the claims under 35 U.S.C. section 103 for obviousness over the combined teachings of Adang, et. al., Schnepf, et. al., and Barnes in view of Klier, Fraley, Rice and Block, establishing a prima facie case of unpatentability. Her Barnes' reference is to the Barnes' Abstract from the Savannah conference in 1985. (Trial tr. Vol. III Part A P.81 L. 9-P.82 L.17).

Mr. Goolkasian was then cross-examined. He testified that an examiner with the United States Patent Office is presumed to be skilled in the art. (Trial tr. Vol. III Part B P.13 L.3). Those substantially involved in the '799 patent, according to Mr. Goolkasian, were the inventors, Dr. Cardoen and Mr. Jansens. (Trial tr. Vol. III Part B P.13 L. 20-P.14 L.1). He believes Mr. Jansens conduct was inequitable because "he culled the data and put in only the good data, and did not include the results that did not show success. And then he made statements to the examiner which indicated that he knew of no results to the contrary. And he made statements to the

examiner with regard to any Bt gene would work in any plant for any bug." (Trial tr. Vol. III Part B P.14 L. 19-24). Mr. Goolkasian also ascribed inequitable conduct to Mr. Jansens for his failure to bring to the attention of the Office the work that had been done in corn with the information he had before him where there were failures in corn. (Trial tr. Vol. III Part B P.15 L. 6-8).

Mr. Goolkasian testified that Dr. Meulemanns committed inequitable conduct in the prosecution of the '565 patent by withholding data from the Patent Office regarding the notes from the Barnes' abstract, and he misrepresented the Barnes' abstract in light of the data he knew and he reiterated the position that "any gene would work in any plant species for any bug." (Trial tr. Vol. III Part B P.17 L. 18-20). After repeated rejections of broad claims by the PTO because of unreliability of expression of the Bt toxin genes in plant cells, and the PTO examiner's conclusion that "[t]he claims recite a Bt insecticidal crystal protein, and applicants have not enabled the claimed invention for all Bt crystal proteins," Bayer submitted a statement to the PTO examiner that, "[t]he problem of unpredictability of expression of foreign genes in plants that the examiner purports to exist has actually been solved by the present invention by providing truncated Bt genes." Based on his role in the prosecution of the '565 patent, all of the knowledge Dr. Meuelemanns possessed along with others at Bayer as chronicled in this opinion concerning all of the failures at Bayer in its research and testing, this was a false statement made to the PTO examiner. The Court agrees with Dr. Goolklisan, that the statement was not true. (Trial tr. Vol. III Part A P.76 L.15-P.78 L. 13).

Appendix F

Mr. Jansens was questioned on re-direct examination, after Mr. Goolkasian's testimony on cross-examination that there was a continuing responsibility of Bayer to supply the United States Patent Office examiner with later discovered material information, and on cross-examination he was unable to cite to any authority supporting his asseveration. Monsanto's counsel presented him the case of *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.3d 801, 803 (Fed. Cir. 1991) for the proposition that "[t]he duty of candor extends throughout the patent's entire prosecution history. In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. 'Claims are not born, and do not live, in isolation. Each is related to the other claims, to the specification and drawings . . . [and] to earlier or later versions of itself in light of amendments made to it. (Internal citation omitted). Therefore, a breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or related application." Mr. Goolkasian confirmed that the argument that no such law existed was incorrect. (Trial tr. Vol. IV Part A P.13 L.4-P.15 L.3).

After Mr. Goolkasian was shown 37 C.F.R. 1.56 which was effective March 16, 1992, there was a proposed amendment which was not adopted. He read the language into the record where the comment was rejected; "[t]he suggestion in the comment is not adopted. The duty to disclose information material to patentability rests on the individuals designated in Section 1.56(c) until the application issues as a patent

or becomes abandoned. Paragraph A of Section 1.56 makes it clear, however, that each individual has a duty to disclose only information which is known to that individual to be material." (Trial tr. Vol. IV Part A P.16 L. 18-25). Mr. Goolkasian concluded that someone like Mr. Jansens who is substantially involved in the prosecution of a patent has a continuing duty which does not terminate upon the filing of a declaration, because the Patent Office does not want to grant invalid patents. Mr. Goolkasian further testified that Mr. Jansens had an obligation to look at all of the facts in his affidavit, to realize that he had to submit both good and bad data, or if there is bad data that can be explained away, then there is a duty to disclose the bad data and explain it away. (Trial tr. Vol. IV Part A P.18 L. 2-19). On the very day Mr. Jansens signed the September 9, 1991 declaration, he received negative test results in corn which he did not report to the United States Patent Office. He said he did not recall if he had received the negative results before or after he signed the declaration. In any event, he did not obey the continuing duty to disclose, as described by Mr. Goolkasian.[15]

---

15. Bayer claims there is no continuing duty of Mr. Jansens to disclose test results after the September 9, 1991 declaration was filed. While these results were acknowledged by Mr. Jansens before the declaration was filed, and after he signed it, the Court wants to make it clearly understood that this Court believes there was a continuing duty to disclose, but the Court's conclusions are made without weighing Bayer's failures to disclose inconsistent or contrary information after the knowingly false, highly material declaration was filed.

Appendix F

CONCLUSION OF LAW

Kingsdown Medical Consultants, LTD. v. Hollister Inc., 863 F.2d 867 (Fed. Cir. 1988) redirected the law of inequitable conduct. In that case, Kingsdown sued Hollister for infringement of multiple claims of its patent for a two piece ostomy appliance used by patients with openings in their abdominal walls for release of waste. The original patent application was filed in February, 1978, and patent '363 was issued on July 17, 1984 after a long prosecution history. Claim 50 was submitted after a series of office actions which was rejected for indefiniteness under 35 U.S.C. § 112. The claim was thereafter amended in an attempt to avoid the §112 rejection. During the time that the appeal of other claims was pending, Kingsdown's counsel "saw a two piece ostomy appliance manufactured by Hollister." Kingsdown employed outside counsel to file a continuation application and withdraw the appeal. Other claims were filed by Kingsdown, submitting a two-column list, "one column containing the claim numbers of 22 previously allowed claims, and the other column containing the claim number of the 21 claims in the continuing application that corresponded to those previously allowed claims. That list indicated, incorrectly, that claim 43 in the continuation application corresponded to allowed claim 50 that had been rejected for indefiniteness under § 112. Claim 43 was renumbered as the present claim 9 in the '363 patent." *Id.* at 870-71. The district court found that the examiner could have relied on the representation that claim 50 and rejected claim 43 corresponded to allowable claim 50 and rejected

Kingsdown's suggestion that the examiner must have made an independent examination of claim 43, citing reasons. The materiality inquiry of the district court was satisfied because, "allowability of claim 50 turned on the amendment overcoming the § 112 rejection in the patent application. Kingsdown's knowledge of materiality was inferred from claim 50's having been deemed allowable in the parent application only after the change in claim language." *Id.* at 871. Then, the district court found 'the deceitful intent element of inequitable conduct, because Kingsdown was grossly negligent in not noticing the error, or, in the alternative, because Kingsdown's acts indicated an intent to deceive the PTO." *Id.* at 871. Additionally, the district court ascribed gross negligence to Kingsdown's patent attorney in not catching the misrepresentation. Additionally, the district court inferred motive to deceive the PTO because Kingsdown's patent attorney had viewed Hollister's appliance after he had amended claim 50 and before the continuation application was filed. The Federal Circuit made factual findings before ruling that patent '363 was unenforceable because of inequitable conduct before the PTO, relating to claim no. 9.

The Federal Circuit ruled,

> Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence. *J.P. Stevens & Co.*,

Inc. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 1559, 223 USPQ 1089, 1092 (Fed.Cir. 1984), *cert. denied*, 474 U.S. 822, 106 S.Ct. 73, 898 L.Ed.2d 60 (1985). The findings on materiality and intent are subject to the clearly erroneous standard of Rule 52(a) Fed.R.Civ.P. and are not to be disturbed unless this court has a definite and firm conviction that a mistake has been committed. *J.P. Stevens*, 747 F.2d at 1562, 223 USPQ at 1094.

"To be guilty of inequitable conduct, one must have intended to act inequitably." *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415, 5 USPQ2d 1112, 1115 (Fed. Cir. 1987). Kingsdown's attorney testified that he was not aware of the error until Hollister mentioned it in March 1987, and the experts for both parties testified that they saw no evidence of deceptive intent. As above indicated, the district court's finding of Kingsdown's intent to mislead is based on the alternative grounds of: (a) gross negligence; and (b) acts indicating an intent to deceive. Neither ground, however, supports a finding of intent in this case.

a. Negligence

The district court inferred intent based on what it perceived to be Kingsdown's gross negligence. Whether the intent element of

> inequitable conduct is present cannot always be inferred from a pattern of conduct that may be described as gross negligence. That conduct must be sufficient to require a finding of deceitful intent in the light of all the circumstances. We are not convinced that deceitful intent was present in Kingsdown's negligent filing of its continuation application or, in fact, that its conduct even rises to a level that would warrant the description "gross negligence."

Id. at 872-873.

The Federal Circuit Court then issued an order, en banc, to resolve conflicting precedents. The en banc Court decided that gross negligence, of itself, is insufficient to justify an inference of intent to deceive. The Court further decided that the inequitable conduct question is equitable in nature and not a question of law. The court also adopted an abuse of discretion review standard. Finally, the court announced that when "a court has finally determined that inequitable conduct occurred in relation to one or more claims during prosecution of the patent application, the entire patent is rendered unenforceable." *Id.* at 877.

In *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), Molins filed a British patent application in the fall of 1965, and filed counterpart applications in the United States for a "batch process." Dennis Whitson, a patent agent working in Molins in-house patent

department, became aware, between the fall of 1967 and April 1968, while the U.S. patent applications were pending, of prior art referenced as the "Wagenseil reference." He concluded that the reference fully anticipated the "batch process" claims initially filed in Great Britain, in the United States and elsewhere. Whiston abandoned all foreign batch process claims, except under the U.S. application because it contained batch process claims and "system 24 claims." The Wagenseil reference was cited to and by several foreign patent offices but not by Molins to the PTO. Patent '563 was issued in the United States in January, 1983. Later, Ivan Hirsh, who assumed Whiston's responsibilities when Whiston retired, learned that the Wagenseil reference had been cited in foreign patent prosecutions, but not to the PTO. Together with John Coventry Smith, Jr., they consulted outside counsel and filed a lengthy prior art statement under 37 C.F.R. § 1.502, for Molins, listing the Wagenseil prior art references together with all other prior art references cited during the foreign prosecution. Another company filed a request for reexamination of the '563 patent in view of several newly-cited prior art references. The examiner filed a final office action in the reexamination stating he had considered all of the cited references and no claims were rejected. In 1986 Molins filed suit against Textron for patent infringement. Textron responded with a summary judgment motion asserting that the patents were unenforceable due to inequitable conduct, in particular because of the concealment of the Wagenseil reference and other information. That summary judgment, and a second one, was denied before the district court which

conducted a bench trial, after which that court held the patents were unenforceable due to inequitable conduct. The court further declared the case to be "exceptional" and awarded attorney fees. On appeal, the Federal Circuit held that applicants[16] for patents and their representatives are required to prosecute patent applications in the PTO with candor, good faith and honesty. A breach of duty constitutes inequitable conduct, which includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information coupled with an intent to deceive. "One who alleges inequitable conduct arising from a failure to disclose prior art must offer clear and convincing proof of the materiality of the prior art, knowledge chargeable to the applicant of that prior art and of its materiality, and the applicant's failure to disclose the prior art, coupled with an intent to mislead the PTO." (Internal citation omitted) *Id.* at 1178. The court observed that materiality of the non-disclosure does not demonstrate the existence of intent.

---

16. Under PTO rules, the duty to disclose information material to patentability rests on the inventor, on each attorney or agent who prepares or prosecutes an application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee, or with anyone to whom there is an obligation to assign the application. *See* 37 C.F.R. § 1.56 (1983). For convenience, we simply refer to "applicant" in this opinion. *See also Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253 (Fed. Cir. 1997)(A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty embodied in 37 C.F.R. § 1.56(a)).

Intent is a separate and essential element of inequitable conduct. "Once threshold findings of materiality and intent are established, the court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred." *Id.* at 1178.

The court explained that "[i]nformation is 'material' when there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.[17]" *Id.* at 1179. If information

---

17. The duty to disclose information material to patentability has been codified in 37 C.F.R. § 1.56 (Rule 56), which was promulgated pursuant to 35 U.S.C. §§ 6 and 131. From 1977 to 1992, Rule 56 defined information as "material" when "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." We have adopted this standard as the threshold standard of materiality. *See LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n*, 958 F.2d 1066, 1074, 22 USPQ2d 1025, 1031 (Fed. Cir. 1992). In 1992, the PTO changed Rule 56 to provide that information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability. 37 C.F.R. § 1.56 (1992). "[A]dministrative rules will not be construed to have retroactive effect unless their language requires this result." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *see also* 57 Fed. Reg. 2021 (Jan. 17, 1992) (PTO notice of

(Cont'd)

allegedly withheld is not as pertinent as that considered by the examiner, then such information is not considered to be material.

The court next turned to the issue of the intent element, recognizing that in *Kingsdown*, the court held that circumstantial evidence cannot indicate merely gross negligence. The court ruled,

> Thus, the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, *viz.*, misleading or deceiving the PTO. In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.

Id. at 1180-81.

Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (Fed. Cir. 1997), involved a dispute

---

(Cont'd)

final rulemaking stating that new Rule 56 will be applicable to all applicants and reexamination proceedings pending or filed after March 16, 1992). The Court makes no comment regarding the meaning of Rule 56.

over safety catheter products. The district court entered a permanent injunction against Becton for infringement of patents and concluded that Critikon did not engage in inequitable conduct. The Federal Circuit reversed the district court's finding of no inequitable conduct. The court recognized the patent applicant's duty to disclose material information to the PTO, but failure to disclose does not necessarily terminate the inquiry. The Court explained, "Once thresholds of materiality and intent have been established, the court conducts a balancing test and determines whether the scales tilt to a conclusion that "inequitable conduct" occurred. (Internal citation omitted). The more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct, and vice versa." *Id.* at 1256. Furthermore, the Court observed, "a good faith explanation for failure to cite a reference is important in the intent to deceive analysis." *Id.* at 1257.

In *Bristol-Myers Squibb Company v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226 (Fed. Cir. 2003), Rhone-Poulenc appealed a district court judgment finding that patents '011 and '277, related to taxol, a cancer chemotherapeutic agent, were obtained by inequitable conduct and consequently, unenforceable. Patent '277 issued June 8, 1993. During the prosecution of the patent in the PTO, the inventors submitted a draft of what later became the published JACS article pertaining to certain limitations involving the drug, to Jacques Pilard, a patent agent employed by Rhone-Poulenc in France. In October, 1995, Bristol filed suit

against Rhone-Poulenc seeking a declaratory judgment that it did not infringe '277 and that that patent was invalid and unenforceable. After another filing by Rhone-Poulenc was consolidated with the declaratory judgment suit, the district judge conducted a two-day evidentiary hearing on claim construction and interpretation of the JACS article, thereafter concluding that the inventors failed to provide material information by not providing the PTO with the JACS article during the prosecution of the '011 patent. After a subsequent four-day bench trial, the "court found by clear and convincing evidence that RPR procured the '011 and '277 patents by inequitable conduct by intentionally withholding material information from the PTO with intent to mislead and, therefore held the '277 patent is unenforceable." *Id.* at 1233. The Federal Circuit set forth the applicable law to be used in analyzing inequitable conduct allegations, then noted, "[o]nce the materiality of the information and RPR's intent to mislead have been established, the court must 'weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred.' Moreover, when balanced against high materiality, the showing of intent can be proportionally less." *Id.* at 1233-34. (Internal citation omitted).

In *Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, LTD.*, 394 F.3d 1348 (Fed. Cir. 2005), Bruno Independent Living Aids, Inc. ("Bruno") manufactured and sold stairlifts to aid mobility-challenged individuals in traversing stairways. Acorn, a competitor of Bruno, was awarded summary judgment

against Bruno in an infringement action. Thereafter, Acorn acused Bruno of intentional withholding of invalidating prior art from the PTO and moved the court for attorney fees under the "exceptional case" standard. The basis for the inequitable conduct determination was Bruno's failure to disclose, to the PTO, information on several invalidating prior art stairlifts Bruno had submitted to the Food and Drug Administration when Bruno had sought approval to sell a stairlift covered by the '405 patent. The district court noted that the FDA disclosure occurred concurrently with the prosecution of the '405 patent and observed the absence of a credible good faith explanation from Bruno for not disclosing the same information to the PTO. The District Court found the case to be exceptional under 35 U.S.C. § 285, based on a determination that Bruno engaged in inequitable conduct while prosecuting patent '405, and Bruno appealed.

Bruno was a case where the Court considered the materiality of a non-disclosure. The Court turned to the issue of Bruno's intent, and concluded that "[i]ntent need not, and rarely can, be proven by direct evidence. Rather, in the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Id.* at 1354. The Court noted, that "Bruno has not proffered a credible explanation for the non-disclosure, and an inference of deceptive intent may fairly be drawn in the absence of such an explanation." *Id.* at 1354-55. (Internal citation omitted).

Appendix F

In *Pharmacia Corp. v. Par. Pharmaceutical*, 417 F.3d 1369 (Fed Cir. 2005), Par Pharmaceutical ("Par") admitted infringement of the '368 and '504 patents in-suit and asserted inequitable conduct by Pharmacia Corporation ("Pharmacia") caused the patents to be unenforceable. "Specifically, Par alleged that the patent applicants issued a declaration and terminal disclaimer during prosecution of the '368 patent with an intent to deceive the Patent Office on a point of material significance." *Id.* at 1371. At trial, the district court found only patent '368 unenforceable due to inequitable conduct.

Paragraph 10 of Pharmacia's declaration states, "[e]ven at dosages at 45 pg the 20-ethyl compound does not cause statistically significant decrease in IOP." *Id.* at 1371. This statement conflicts with an article co-authored by the declarant and with two Japanese articles cited in the declarant's article. Pharmacia did not bring these three articles to the attention of the PTO which stated that a compound *causes* a statistically significant IOP reduction without appreciable ocular side effects. Pharmacia's declaration states that the compound *does not cause* a statistically significant decrease in IOP. Irrespective of Pharmacia's explanations, the district court found that the declarant submitted a declaration to the PTO "that he knew or should have known" was inaccurate and misleading, that the misleading declaration was crucial to overcoming the PTP's rejection over the Ueno patent and was thus highly material. "Based on these circumstances, the district court inferred intent." *Id.* at 1372. The district

court then found clear and convincing evidence that the '368 patent was unenforceable due to inequitable conduct. The Federal Circuit affirmed the district court's finding that the '368 patent was unenforceable due to inequitable conduct.

In *M. Eagles Tool v. Fisher Tooling*, 439 F.3d 1335 (Fed. Cir. 2006), the Federal Circuit reversed district court decision granting summary judgment in favor of M. Eagles Tool Warehouse. The district court had found the '914 patent unenforceable due to inequitable conduct. The Federal Circuit found, "[b]ecause there was no clear and convincing evidence demonstrating an intent to engage in inequitable conduct, we reverse the district court's grant of S & G's motion for summary judgment of inequitable conduct." *Id.* at 1336. The Federal Circuit recognized that not only patent applicants, but "those substantively involved in the preparation of prosecution of a patent owe a 'duty of candor and good faith' to the PTO." *Id.* at 1339. The Court observed, "[i]ntent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Id.* at 1340. The Court concluded, "We agree with Astro and conclude that a failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of good faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent." *Id.* at 1339-41.

Appendix F

In *Ferring B.V. and Aventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, 437 F.3d 1181 (Fed.Cir. 2006), Ferring B.V. and Aventis Pharmaceuticals, Inc. ("Ferring") sued Barr Laboratories, Inc. ("Barr") for infringement of patent '398. Barr moved for summary judgment, claiming patent '398 was unenforceable because of inequitable conduct. The Federal circuit affirmed the district court's grant of summary judgment on the ground of unenforceability of the patent for inequitable conduct. On December 17, 1985, Hans Vihardt and Helmer Hagstam applied for the '398 patent. Vihardt and his counsel appeared before patent examiners on May 28, 1986 to discuss prior art references including U.S. Patent '471, of which Ferring was the exclusive licensee until it expired in 1987. Patent 471 taught that "1-deamino-8-D-arginine vasopressin" maybe used for "... peroral ... application." Examiners were concerned that the '491 disclosure of "peroral" application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption. Vihardt argued that the term "peroral" as used in '491 taught absorption through the walls of the mouth. The examiners suggested that the applicants get evidence from a "non-inventor to support their interpretation of the term "peroral." On June 12, 1986, Vilhardt submitted four declarations including two from himself, one from Dr. Myron Miller and one from Dr. Paul Czernichow, relying on the writer's scientific belief that "perorial," in the '491 Patent, meant that the compound could be administered through the mouth, but only for absorption through the cheek of the mouth or under the tongue. The declaration did not disclose

that Dr. Paul Czernichow, one of the declarants, had been receiving research funding from Ferring from 1985-86. Notwithstanding the declarations, the examiners rejected certain claims of the '398 Patent. On November 13, 1987, the inventors appealed the rejection to the Board of Patent Appeals and Interferences, and while the Board accepted the declarants' view that as a general rule, "peroral" administration of a peptide would not be read in the art as suggesting the administration for gastrointestinal absorption, it determined that the applicants' claims were obvious over the '491 patent in light of an article written by Ivan Vavra in 1973, thus affirming the examiners' obviousness objection. Going back to the examiners, the applicants submitted five more declarations to try to persuade that the Vavra reference, when read with the '491 patent, would not suggest gastrointestinal absorption of the peptide. Again, the applicants did not inform the examiners of the Czernichow receipt of money from Ferring. Additionally, the applicants did not inform the examiners that Robinson, one of the new declarants, had been Ferring's pre-clinical research director from 1985-86, and was a paid consultant for Ferring from 1986-89. Furthermore, no disclosure was made that Barth, another new declarant, worked on projects funded by Ferring between 1984-87. Vihardt also admited that he gave Barth some lines, telling him what he should describe in the affidavit. After these declarations were submitted, the examiners allowed the previously rejected claims, and the '398 Patent issued September 10, 1991.

Appendix F

Ferring exclusively licensed the right to market and sell its patented antidiuretic compound to Aventis. Barr filed an Abbreviated New Drug application with the Food and Drug Administration seeking approval to market a generic version of the compound. Barr filed a statement that the relevant patents to the generic compound were either invalid or would not be infringed. Ferring responded with an infringement action and Barr filed a motion for summary judgment based on inequitable conduct and non-infringement which the district court granted on both grounds. The district court reasoned, in part, that "it must have been clear to Dr. Vihardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for the purposes of obtaining *objective evidence* that the invention was not anticipated by the prior art or obvious." *Id.* at 1186. (Emphasis in original).

The Federal Circuit held, "The inequitable conduct analysis is performed in two steps comprising 'first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is *so culpable* that the patent should be held unenforceable.' " *Id.* at 1186-87.

Judge Newman, in a strong dissenting opinion, concludes that the majority opinion rejects the teachings of *Kingsdown Medical consultants, LTD. v. Hollister Incorporated*, 863 F.2d 867 (Fed. Cir. 1988), which he believed corrected widespread abuses of the use of the

inequitable conduct defense, by applying instead, "objective standards and reasoned perspective to the charge of inequitable conduct." *Id.* at 1196. He notes that *Kingsdown* established that negligence alone would no longer support a holding of inequitable conduct, and believes that the majority opinion restores a "casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a 'should have known' standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence." *Id.* at 1196.

In *Purdue Pharma, L.P. et. al. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006), Purdue Pharma filed suit against Endo Pharmaceuticals for patent infringement, alleging the latter's version of OxyContin infringed its three patents. Endo Pharmaceuticals counterclaimed alleging that Purdue Pharma's patents were invalid because of inequitable conduct. The district court found there was inequitable conduct because of material misrepresentation to the PTO by Purdue Pharma. Before reversing the district court's judgment of the inequitable conduct finding, the Federal Circuit observed,

> [o]nce threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred. This requires a careful balancing: When the misrepresentation or withheld information is highly material, a lesser

> quantum of proof is needed to establish the requisite intent. In contrast, the less material the information, the greater the proof must be. *Id.* at 1128-29. (citation omitted).

The Court then found that the Plaintiff had satisfied its burden of proof on the issue of existence of materiality, but noted that the district court may have believed there was a high level of materiality which might have influenced the finding of intent to deceive. The Federal Circuit found, "we stress that the level of materiality is not especially high," and the district court "may have erred to the extent it relied on a high level of materiality in determining whether Purdue intended to deceive the PTO and whether Purdue ultimately committed inequitable conduct." *Id.* at 1133. Later in the opinion, the Court stated, "[i]t is true that in some cases this court has inferred the requisite intent to deceive when a patentee has withheld highly material information such as a key prior art reference and knew or should have known of its materiality." *Id.* at 1134.

The Court referenced the post-1992 "current rule" for defining "materiality" as follows: [I]nformation is material to patentability when: [I]t is not cumulative to information already of record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability.

Appendix F

This definition is to be observed for applications pending or filed after March 16, 1992.

The Federal Circuit was unable to uphold the district court's finding that Purdue intended to deceive the PTO when it failed to disclose that its "surprising discovery" of the reduced dosage range was based only on an "insight." The case was remanded to give the district court an opportunity to reconsider its intent finding.

Monsanto v. Bayer Bioscience N.V., 363 F.3d 1235 (Fed. Cir. 2004) reversed this Court in its flawed ruling finding inequitable conduct in a summary judgment in favor of Monsanto. The Federal Circuit noted that "[t]o show intent to mislead, Monsanto must show by either direct or indirect evidence that when Mr. Jansens attested that he knew 'of no test results which are contrary to or inconsistent with the test results [submitted to the PTO] or which would lead to different conclusions from those expressed' in the declaration, he knew the statement was false or misleading." *Id.* at 1241. The court further noted that "[t]he circumstances surrounding the submission of the declaration are certainly relevant to the inquiry into intent, which ordinarily cannot be established by direct proof and must be inferred from an assessment of all of the surrounding circumstances. *See also Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989). (*Id.* at 1241). Mr. Jansens has now testified extensively. The Court finds by clear and convincing evidence that when Mr. Jansens attested that he knew of no test results which "are contrary to or inconsistent

with the test results submitted to the PTO examiner or which would lead to a different conclusion from those expressed in the declaration," he knew the statements were false and misleading and he knowingly made the statements with the specific intent to deceive or mislead the PTO examiner. Mr. Jansens' explanations for not submitting known negative tests are not believable. His testimony that he did not intend to mislead the PTO examiner is not believable. His testimony that he knows of no test results contrary to or inconsistent with test results submitted to the PTO examiner or which would lead to a different conclusion from those expressed in the declaration is not believable.

Kao Corporation, et al., v. Unilever United States, Inc., et al., 441 F.3d 963 (Fed.Cir. 2006) reports an appeal from a district court ruling that plaintiff's patent was valid and enforceable, but not infringed by Unilever's product. The dispute involved patent rights to a cosmetic skin care product that removes blackheads. The district court found no inequitable conduct by Plaintiff.

Unilever charges two grounds for inequitable conduct relief. The first is that Kao provided the PTO examiner with misleading test results for the claimed coopolymer in a 1998 declaration, wilfully failing to report the test results of one variant of "PVM/MA,Gantrezt AN-119," which reported "substantially weaker results than were reported for another variant, 'AN-169.'"

> The record indicates, however, and the trial court found, that the Second Uemura

> Declaration selectively disclosed only the most positive available data. It failed to reveal several significant facts: first, that the inventors also tested a low molecular weight PVM/MA variant, AN-119, which only achieved a removal ratio of 14.4%; and second, that the inventors did not disclose the margins of error for their tests, which were 7.1% for the AN-169 and 5.2% for the AN-119. In depositions, the inventors were unable to offer any explanation for their failure to report all the results. *Id.* at 539-40. Moreover, the Second Uemura Declaration also contains a statement that "there is no reason to expect any significant difference in keratotic plug removal for other polymers within the claimed genus."

Id. at 971.

The district court found that the omission was material, but it was not made with the intent to deceive. The Federal Circuit ruled that

> Intent to deceive "cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Purdue Pharma*, 438 F.3d at 1134. Here, although there certainly was evidence from which the trial court could have concluded that Kao acted with intent to deceive, we are very reluctant

> to question the judgment of the finder of fact, who appears to have considered the relevant evidence-including the rather glaring failure of the inventors to offer any rationale for the omission-in rendering the decision. *See id.* (declining to infer intent to deceive in similar circumstances). The trial court evidently placed considerable weight on the fact that Kao did eventually submit most of the omitted data to the examiner. Given a blank slate, we might weigh the evidence differently. Given the limited scope of our review, however, we cannot second-guess the trial court's decision.

Id. at 972.

DISCUSSION

This case has been pending before this Court for a very long time, in part, because of this Court's errors. In any ruling or reference made herein, it must be clearly understood, that attorneys for both parties, who have borne substantial burdens in complying with the Court's orders, have made an enduring impression by always observing the highest tenets of professionalism, and they have displayed mutual respect for their worthy adversaries and for the Court. Any findings of inequitable conduct or actionable conduct of any kind is ascribed to no lawyers in the jury trial or in this equitable proceeding. All have recognized the bounds of effective advocacy and have practiced their very substantial skills in representing their clients in the most appropriate manner.

Appendix F

Monsanto sought declaratory relief in this Court in late 2000 that neither Monsanto nor its licensees of MON 810 YieldGuard® products infringed United States Patents 5,254,799 ('799); 5,545,565('565); 5,767,372 ('372) and 6,107,546 ('546). Monsanto argued that those patents were unenforceable because of inequitable conduct. In its counterclaim, Bayer alleged Monsanto's infringement of Bayer's patents. On December 29, 2002, this Court erroneously granted summary judgment in favor of Monsanto on its claim of inequitable conduct. The Federal Circuit found that factual issues existed which this Court did not appropriately consider, and remanded the case for action by this Court consistent with the terms of the remand order. Bayer then dismissed the '799, '372 and '546 patents (regarding plant claims) from the case, leaving the '565 patent (chimeric gene claims) for litigation on remand. Following remand, Bayer sought and received summary judgment from this Court that the circumstances of the Jansens' declaration could not impact the '565 patent based on infectious unenforceability. A jury verdict was returned on November 22, 2005 finding that Monsanto's MON 810 Bt corn did not infringe Bayer's '565 patent; the claims of Bayer's '565 patent were invalid because of prior inventorship, and the Bayer '565 patent was invalid for obviousness in view of prior art. Monsanto's instant claim for relief for alleged inequitable conduct by Bayer and its predecessor entities, includes Bayer's (1) misrepresentations and omissions related to the Stefan Jansens' declaration of September 9, 1991 calling for judgment that patents '799, '372 and '546 are invalid

and unenforceable, (2) continued misrepresentations and omissions regarding the scope of enablement during the prosecution of the '565 patent and (3) misrepresentations and omissions related to the Barnes publications during prosecution of the '565 patent so that under charges of (2) and (3), the '565 patent is invalid and unenforceable. A hearing before this Court was conducted from February 21, 2006 to February 24, 2006 on the inequitable conduct issues. Closing arguments on Bayer's Motion For Judgment As A Matter Of Law and on inequitable conduct issues were heard May 5, 2006. A requested briefing schedule was granted.

This is a case more about Bayer's officials involved in the application process of patenting its Bacillus thuringensis (Bt) products, and in particular the '799 patent and the '565 patent, than just the September 9, 1991 false and misleading declaration of its entomologist, Stefan Jansens, which was drafted and submitted with the intent to deceive and mislead the United States Patent Office Examiner. The orchestration of deceit, of purposeful misrepresentation of material fact, of intentional non-disclosure of material information, and submission of false material information, with intent to deceive and mislead the United States Patent Office Examiner has been proved by clear and convincing evidence. The weighing of equities of the parties clearly and convincingly warrants a conclusion that Bayer and its antecedent companies committed inequitable conduct before the United States Patent Office in the prosecution of the '799 patent, the '372 patent, the '546 patent and the '565 patent.

Appendix F

Patents are presumed to be valid. Vast resources are expended in developing new products, and the human and financial sacrifices required in obtaining a United States patent must be rewarded and the novelty of imagination protected. A natural tension in the law exists, because the PTO personnel, in examining patent applications, utilizing substantial skills in allowing legally justified claims under close scrutiny to protect other rightful claim holders and inventors, while making decisions in claim allowance so the human and financial development costs will be protected from subsequent determinations of invalidity which destroys very significant efforts by the putative inventors and the PTO. To assure valid patents are issued, examiners rely upon candor and good faith of inventors and others prosecuting claims in the PTO to supply truthful information, so the interests of other rightful inventors, claimants, financial investors, the PTO, American citizens and foreign patent holders and inventors will be safeguarded. Validly presumed patents stand on one end of the fulcrum, and candor and good faith are the balancing weight on the other end. When balanced, all interests are protected. The duty of candor and good faith may be breached, and when that is suspected, others with rights to be protected may rely upon an equitable remedy for relief.

Because of the presumption of the validity of issued patents, the law recognizes the arduous tasks involved in getting to the point where a patent is issued by the PTO. Thus, the presumption of validity is not to be lightly abrogated. An issued patent should not be invalidated

unless stringent standards have first been legally satisfied. The equitable remedy to address invalidity of a presumed valid patent is created upon a finding of "inequitable conduct." In the lexicon of developed law on the doctrine of inequitable conduct, abuses in the advancement of this doctrine have been observed. "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *See Burlington Industries, Inc. v. Dayco Corporation*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Fortunately, the law in this field is well-defined. Imposition of a judgment invalidating a patent by finding existence of inequitable conduct is to be considered under very limited circumstances.

The '799 patent

The following recitation does not include all factual findings upon which the Court's conclusions are based. Instead, the Court relies on all of the findings of fact stated in this opinion. The following statement of facts is only a brief summary.

As already observed, Bayer suffered repeated rejections of the broad claims it sought. A few months before the Jansens' declaration was signed and submitted to the PTO, Dr. Cardoen, who was involved with prosecuting the '799 patent, declared, after another rejection, "it appears we are back to square one." At a meeting attended by Mr. Jansens, Dr. Cardoen said that the PTO examiner urged Bayer to limit its claims to the Bt gene in tobacco. Bayer could accept the limited

approval of the PTO examiner, or take action to gain approval of the long sought after broader claims that had been repeatedly rejected. Armed with the Jansens' declaration, Bayer argued to the PTO examiner, in the absence of any other newly discovered evidence, than the submission of the Jansens' declaration, that the broader claims should be allowed. The long-sought broader claims were allowed a few months later. Mr. Jansens acknowledged that there was pressure at Bayer to get patent approval for the broader claims. The Jansens' declaration was submitted at a frenetic period when Bayer officials recognized that competitors were making landmark advances in insect control with gene expression in plants. Mr. Jansens acknowledges that his declaration was important in getting approval of the broader claims. Mr. Jansens knew his declaration was material. This Court rejects Bayer's assessment that the Jansens' declaration was not highly material. Mr. Jansens' efforts to customize his live testimony to rebuke his own prior deposition testimony does not pass without notice. As recognized above, Mr. Jansens has no compunction against altering the facts, in testifying, to suit the demands of his company. He unequivocally testified in his deposition that in some tests in potato, and in tests in cabbages, cotton and corn, there was no insect controlling amount of Bt protein reported, and that the results were not in his declaration. Bayer's attempts to establish subjective good faith sufficient to overcome the intent to mislead is not persuasive.

The Court will first decide if the representations made by Stefan Jansens to the PTO and the information

he withheld from the PTO were material. Mr. Jansens' made a sworn statement in his declaration representing to the PTO, in particular, that he knew of no test results contrary to or inconsistent with those submitted to the PTO examiner which would lead to a different conclusion from those expressed in the declaration. Mr. Jansens knew the declaration was false. Additionally, the Court finds by clear and convincing evidence that there is a substantial likelihood that a reasonable examiner would have considered Mr. Jansens's withholding of known contrary negative test results important in deciding whether to allow the application to issue as a patent. Bayer submitted a known false declaration, and Bayer failed to disclose material information.

The Court has considered the definition of materiality as it is known under the "current rule." *See Purdue Pharma, L.P. et. al. v. Endo Pharmaceuticals, Inc.*, 438 F. 3d 1123, 1129 (Fed. Cir. 2006). Had Jansens truthfully included in the September 9, 1991 declaration, the tests he knew were contrary to or inconsistent with tests he reported in the declaration, the declaration would have been inconsistent with the position of Bayer in asserting an argument for patentability. The information was not cumulative to information already of record in the application. Additionally, test results of many tests performed by Mr. Jansens that were undisclosed in his declaration which contradict his conclusions in his declaration constitute information that is inconsistent with the position Bayer took in asserting an argument of patentability. Also, the undisclosed information establishes a prima facie case of

unpatentability. Indeed, the reason for submitting the Jansens' declaration was to overcome the Examiner's concern about enablement. Bayer made a deliberate decision to withhold the known negative tests from the PTO. The Court finds by clear and convincing evidence that the submission of the known false declaration was highly material.

The Court finds by clear and convincing evidence that Mr. Jansens knew the statements in his declaration to the PTO examiner were false and misleading and he knowingly made the statements with the specific intent to deceive or mislead the PTO examiner. Bayer intended to act inequitably. Bayer had the specific intent to accomplish the act of having the PTO examiner favorably grant Bayer's broad claims, which Bayer ought not to have done under the facts and circumstances of this case, particularly in view of the submission of the false Jansens' declaration. The Court finds by clear and convincing evidence that Mr. Jansens withheld submitting the negative test results by a deliberate decision to withhold known highly material information from the PTO examiner. The Court finds by clear and convincing evidence that Bayer had the specific intent to accomplish the act of having the PTO examiner favorably grant Bayer's broadly sought claims which Bayer ought not have done under the facts and circumstances of this case, in particular because of the intentional withholding of negative test results by Bayer. Bayer's attempt to establish subjective good faith sufficient to overcome the intent to mislead is not persuasive.

Appendix F

The Court has weighed the materiality and intent to deceive or mislead, in light of all of the circumstances in the case, and finds by clear and convincing evidence that the equities warrant a conclusion that Bayer's conduct is so culpable, that Bayer committed inequitable conduct in submitting the knowingly false Jansens' declaration, and in failing to disclose to the PTO known negative tests which would have refuted Bayer's claims. The '799 patent, the '372 patent and the '546 patent are accordingly unenforceable.

The '565 Patent

First, the Court rejects Monsanto's inference that because the same PTO examiner handled the '799 patent and the '565 patent, the Jansens' declaration may have had significance in the '565 patent prosecution history. That conclusion requires the Court to speculate. That proposition does not bear on the Court's conclusions.

There is no dispute that Dr. Meulemanns had primary responsibility with Bayer to assist attorneys in the prosecution of the '565 patent. He reviewed information submitted to the United States Patent Office to determine if it was technically correct from a scientific level, to determine if the correct terminology was used and to check for accuracy. Repeated rejections for enablement of the '565 patent by the PTO examiner are documented. Because of the highly unpredictable nature of expression of Bt genes in plants, it did not appear that any Bt toxin would be effective in any plant

cell against any species of insect, the examiner rejected Bayer's broad sought after claims for lack of enablement. The Court disagrees with Bayer's argument that Bayer, in submitting a statement to the PTO that its invention had solved the problem of the unpredictability of expression of Bt genes in plants, made only a statement that should be excused as a statement of advocacy. Bayer falsely argued to the PTO examiner that "[t]he problem of unpredictability of expression of foreign genes in plants, that the Examiner purports to exist, has actually been solved by the present invention by providing truncated Bt genes." This was false information. Dr. Meulemanns knew this information was false. Dr. Meulemanns, for reasons already assigned, does not present himself as a generally believable witness in this litigation. Clearly, he was the one in the position of responsibility to orchestrate this argument to the PTO. He knew of the many repeated failures of Bayer scientists to achieve Bt insect control in cabbages, cotton and corn. Dr. Meulemanns knew that Bayer had not solved the problem of the unpredictability of expression of Bt genes in plants. The Court finds by clear and convincing evidence that there is a substantial likelihood that a reasonable examiner would have considered the false statement important in deciding whether to allow the application to issue as a patent. Under the *Purdue* standard for materiality, had Dr. Meulemanns made a truthful statement to the PTO examiner that the problem of unpredictability of expression of foreign genes in plants had not been solved, the information would by itself establish a prima facie case of unpatentability. The information would not

be cumulative to information already of record in the application. This falsely submitted information to the PTO was highly material.

The Court finds by clear and convincing evidence, for all of the reasons stated above, that Bayer knew, when the representation was made that unpredictability of gene expression had been solved, that the representation was false and misleading, and that it was submitted to the PTO examiner with the specific intent to deceive or mislead the PTO examiner. Bayer intended to act inequitably. Bayer had the specific intent to get broad claims approved by the PTO which Bayer ought not to have received, under all of the facts and circumstances of the case.

As explained above, the Wayne Barnes abstract from the Savannah, Georgia conference was submitted as prior art in the '565 application, but the Dr. Celesta Mariani notes taken from a poster at the Barnes display were not submitted as prior art. Bayer argues the notes show nothing material, that without interpretation, they are meaningless, that Dr. Meulemanns did not know of the contents of the notes, and even if they had been disclosed, which there was no duty to do so, the Barnes abstract explained away any necessity to disclose confusing and unreliable information in the notes which, in any event, did not identify a gene. Bayer has an enormous credibility problem on this point, in this litigation, inherited primarily from Dr. Meulemanns, but to a lesser extent from Dr. Mariani. She took thorough notes which have been clearly deciphered by others.

Dr. Meulemanns testified that he talked to Dr. Mariani about the notes, but she could recall little or nothing about them. The lengthy recitation above, from Dr. Mariani's deposition, demonstrates that she recalls a great deal about the notes and is quite able to explain them in detail. At trial, she attempted to downplay her understanding of the notes and her ability to recall what they report, and their significance. She said in her deposition, that she thought she was doing something beneficial when she took the notes, but later realized the notes might be detrimental.

The Court is entitled to consider the motives of witnesses when testifying. Dr. Meulemanns' and Dr. Mariani's testimony is considered in light of motives they have to protect Bayer. The Court will not repeat the lengthy Mariani recitation from above, but it is clear that the Barnes notes coded for the same 67 Kd toxic protein Bayer wanted to claim, that the Barnes gene was 3.4 Kb for the full length, that because of the identified xho site, it would be easy to determine the identity of the Bt gene being used, and the chimeric gene used was toxic to insects by the drop. There is a substantial likelihood that a reasonable examiner would have considered the Barnes notes important in deciding whether to allow the application to issue as a patent. Under *Purdue*, The Barnes notes by themselves, withheld by Bayer from the PTO examiner, if disclosed, would establish a prima facie case of unpatentability of Bayer's claims under the '565 patent. The information was not cumulative to information already of record in the application. It was submitted at a time when the

PTO had rejected Bayer's claims under the '565 patent. Bayer's competitors were, as Dr. Meulemanns knew, making landmark progress in the transformation of insect controlling plants in wide-ranging crops. The Barnes notes are highly material. Bayer's attempts to establish subjective good faith sufficient to overcome the intent to mislead is not persuasive.

The Court finds by clear and convincing evidence that for all of the reasons cited in this opinion, Bayer knew, when the Barnes' notes were not disclosed to the PTO examiner, that Bayer was making a deliberate decision to withhold the known highly material reference with the specific intent to deceive or mislead the PTO examiner. Bayer had the specific intent to get broad claims approved by the PTO examiner which Bayer ought not have received, considering all of the facts and circumstances of this case.

The Court has weighed the materiality and intent to deceive or mislead the PTO examiner, in light of all of the facts and circumstances of this case, and finds by clear and convincing evidence that the equities warrant a conclusion that Bayer's conduct is so culpable, in submitting a known false statement to the PTO, concerning solving the unpredictability of gene expression in plants, and in intentionally not disclosing the Barnes notes as prior art to the PTO, that Bayer committed inequitable conduct, and the '565 patent is unenforceable.

Accordingly,

IT IS HEREBY ORDERED that U.S. Patents 5,254,799; 5,767,372; 6,107,546; and 5,545,565 are unenforceable due to Bayer's inequitable conduct during patent prosecution.

IT IS FURTHER ORDERED that Bayer's Post-Trial Motion for Judgment as a Matter of Law [doc. #867] is **DENIED.**

Dated this *28th* day of August, 2006.

s/ E. Richard Webber
E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE

APPENDIX G — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI, EASTERN DIVISION DATED JANUARY 10, 2005

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

Case No. 4:00CV01915 ERW

MONSANTO COMPANY,

Plaintiff,

vs.

BAYER BIOSCIENCE, N.V.,

Defendant.

MEMORANDUM AND ORDER

This matter comes before the Court upon additional briefing ordered by this Court on June 2, 2004 [doc. #440]. The Court will treat the issue as a motion for summary judgment.

I. PROCEDURAL BACKGROUND

As originally filed, this case involved allegations of invalidity, unenforceability and infringement of four United States patents assigned to Defendant, Bayer Bioscience, N.V. [Bayer] and its predecessors - U.S.

Appendix G

Patents Numbers 5,254,799 [the '799 patent]; 5,545,565 [the '565 patent]; 5,767,372 [the '372 patent]; and 6,107,546 [the '546 patent] [collectively referred to as "patents-in-suit"]. The product accused of infringement in this case is an insect resistant corn seed product known as MON810 corn, which is sold by Monsanto and its licensees.

On July 14, 2002, Monsanto moved for summary judgment that all patents-in-suit were unenforceable because of an allegedly false and misleading declaration signed by Bayer's Stefan Jansens which was submitted during prosecution of the '799 patent. Monsanto asserted that the '565, '372 and 546 patents were similarly unenforceable under the doctrine of infectious unenforceability. On December 27, 2002, this Court granted Monsanto's motion for summary judgment and held all of the patents-in-suit unenforceable as a result of the inequitable conduct with respect to Jansens' declaration.

The United States Court of Appeals for the Federal Circuit reversed and remanded this Court's summary judgment determination of unenforceability of the four patents. *Monsanto v. Bayer BioScience N.V.*, 363 F.3d 1235, 1240-42 (Fed. Cir. 2004). In its decision, the Federal Circuit held:

> it is a disputed question of fact as to whether Mr. Jansens' affidavit and his deposition testimony are inconsistent. At his deposition, Mr. Jansens was asked whether he submitted

the test results in question. He admitted he had not submitted those results. When asked whether he thought he should have submitted them, he replied that as an entomologist it was difficult for him to determine what information the patent office would want. On remand, the district court may consider, in light of all the evidence, whether there is conflict between Mr. Jansens' statements at his deposition and the statements in his affidavit, and if so, whether and to what extent his affidavit should be discounted as a result of the conflict.

Because Mr. Jansens' affidavit sets forth a non-frivolous explanation that could lead a finder of fact to determine that his declaration was not false or misleading, the affidavit created a disputed issue of material fact as to whether the declaration was false or misleading. To show intent to mislead, Monsanto must show by either direct or indirect evidence that when Mr. Jansens attested that he knew "of no test results which are contrary to or inconsistent with the test results [submitted to the PTO] or which would lead to different conclusions from those expressed" in the declaration, he knew the statement was false or misleading.

Id. at 1241-42.

Appendix G

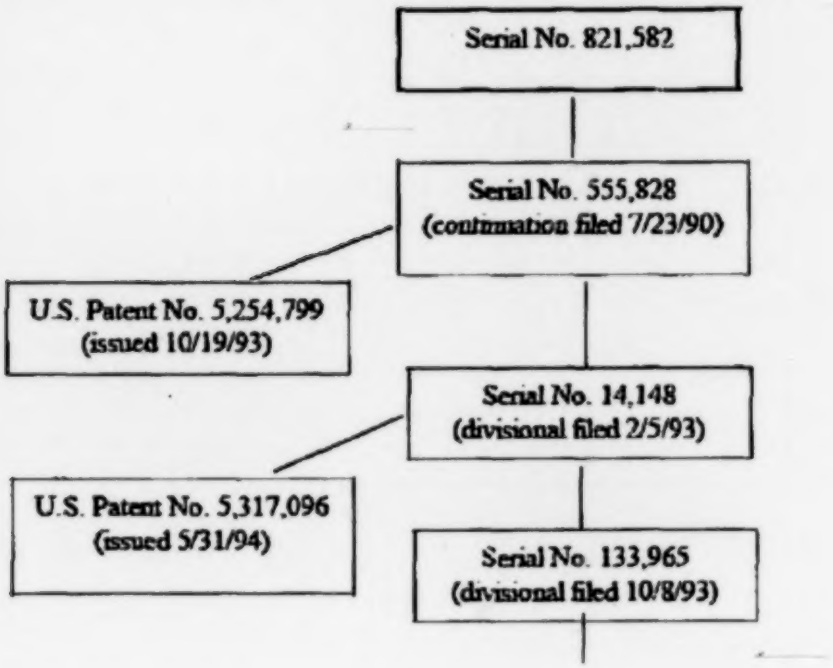
After so indicating its intent at a June 1, 2004 scheduling conference, Bayer withdrew the '799, '372 and '546 patents, leaving just the '565 patent in the case. That Statement of Non-Liability was filed with the Court on June 22, 2004 thereby removing any case or controversy with respect to all patents except the '565 patent. Also, at the June 1, 2004 scheduling conference, Bayer argued that the inequitable conduct with respect to the Jansens' declaration allegedly was not material to the prosecution of the '565 patent and hence could not affect that patent under the doctrine of infectious unenforceability. Accordingly, the Court received briefing by the parties on this issue and conducted a hearing on June 20, 2004 directed to the infectious unenforceability issues insofar as they could affect the '565 patent.

Monsanto has not argued that Bayer committed inequitable conduct in prosecuting the '565 patent. The issue presently before the Court is whether the Jansens' declaration was material to the prosecution of the '799 patent such that the doctrine of infectious unenforceability could affect the enforceability of the '565 patent should the Jansens declaration be found to have been false or omitted relevant adverse information and was submitted with the intent to deceive the patent examiner.

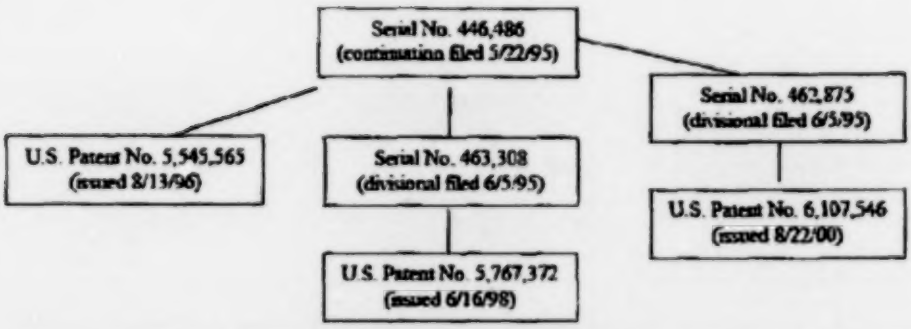
Appendix G

II. FACTUAL BACKGROUND

All of Bayer's patent applications are generally directed to technology involving truncated genes encoding insecticidal proteins of *Bacillus thuringienses* ("Bt") bacteria and their expression in plants. The priority tree for all the patents is diagramed below:



Appendix G



The claims of what are now patent '565 and patent '799 were once part of the same patent application. However, the United States Patent and Trademark Office [PTO] requires that "[i]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." 35 U.S.C. § 121 (2004). The PTO issued a so-called "restriction requirement" directing that the chimeric gene claims (some claims now in patent '565) were a distinct invention from the plant and plant cell claims (now in patent '799). Bayer cancelled the claims in the '799 patent application relating to chimeric genes.

After cancelling the chimeric gene claims in the '799 patent application, Stefan Jansens submitted a declaration in support of the '799 patent swearing under oath that

> [i]n order to demonstrate that generally any truncated Bacillus thuringiensis ("Bt") gene could be expressed in generally any plant to provide an insect controlling amount of its

> encoded Bt polypeptide toxin in the so-transformed plant as disclosed in this application, the following tests were carried out under my supervision . . . The test results . . . demonstrate that any truncated Bt gene can generally be used to provide an insect controlling amount of the encoded Bt polypeptide toxin in generally any plant transformed with the truncated Bt gene . . . I know of no test results which are contrary to or inconsistent with the test results set forth . . . or which would lead to different conclusions from those expressed [in this declaration].

The '799 patent issued October 19, 1993. After the issuance of the patent it was later learned that Mr. Jansens' declaration refers to positive test results for controlling insects using truncated Bt in tobacco, tomato, and potato, but Mr. Jansens also supervised tests on cabbage, cotton, corn, and occasionally potatoes and tomatoes, that produced negative results that he did not disclose to the PTO.

Ultimately, the chimeric genes claims "restricted out" of the '799 patent resulted in divisional patents. A divisional patent is issued "for a distinct or independent invention, which is carved out of the pending parent application and which claims only subject matter disclosed in the parent application . . . [D]ivisional applications are filed voluntarily or as a result of an examiner's ruling against the joinder of separate inventions in a single application." Jane E. Lehman, Anne E. Melley & Elizabeth A. Brainard, *Types of Continuing Applications*, 60 Am. Jur.2d Patents § 325

Appendix G

(2004). One of the divisional patents issued was patent '565 which was specifically limited to portions of the SEQ ID No. 1 protein or nucleotide sequence. Patent '565 issued in 1995. A side-by-side comparison of the first claims of patent '799 and patent '565 illustrates the distinctness of the inventions.

Patent '799	Patent '565
1. A plant cell susceptible to transformation by Agrobacterium, the genome of which contains a chimeric gene comprising:	1. A chimeric gene comprising:
a) a first DNA fragment that encodes a N-terminal fragment of approximately 60-80 kD, derived from DNA encoding a Bacillus thuringiensis insecticidal crystal protein of approximately 130 kD which has been truncated; and	(1) a DNA fragment encoding an insecticidal Bacillus thuringiensis Bt2 toxin of about 60 to about 80 kD, wherein said Bt2 toxin comprises the amino acid sequence of SEQ ID No. 1 from amino acid position 29 to amino acid position 607; and
b) a promoter region and a 3' non-translated region containing a polyadenylation signal; the first DNA fragment being under the control of the promoter region; the promoter and 3' non-translated regions allowing the first DNA fragment to be expressed in the cell; whereby the chimeric gene can be expressed in the cell as an insect controlling amount of an insecticidal Bacillus thuringiensis polypeptide toxin with toxicity to Lepidoptera insects.	(2) a promoter region of a gene naturally expressed in plant cells, wherein said DNA fragment is under the control of said promoter region

III. STANDARD OF REVIEW

Summary judgment pursuant to Federal Rule of Civil Procedure 56(c), shall be granted "forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c), *quoted in Crater Corp. v. Lucent Tech., Inc.*, 255 F.3d 1361, 1366 (Fed. Cir. 2001) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986), and *Dammen v. Unimed Medical Center*, 236 F.3d 978, 980 (8th Cir. 2001)). *See also Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550 (Fed. Cir. 1995) (stating that for general procedure and practice under Rule 56 in patent cases, the Federal Circuit looks to the law of the regional circuit). The United States Supreme Court has noted that "[s]ummary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex*, 477 U.S. at 327 (quoting Fed. R. Civ. P. 1). Unless a reasonable jury could return a verdict for the non-moving party, summary judgment is appropriate. *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1319 (Fed. Cir. 2002).

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is

material to a judgment in its favor. *Crater Corp.*, 255 F.3d at 1366 (citing *Celotex*, 477 U.S. at 323,-24). The burden then shifts to the non-moving party who must set forth specific evidence showing that there is a genuine dispute as to material issues. *Id.* (citing *Anderson v. Libert Lobby, Inc.*, 477 U.S. 242, 250 (1986). To meet its burden, the non-moving party may not rest on the pleadings alone and must "do more than simply show there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

In analyzing summary judgment motions, "all of the non-movant's evidence is to be credited, and all justifiable inferences are to be drawn in the nonmovant's favor." *Netscape*, 285 F.3d at 1319; *see also Morris v. Crawford County*, 299 F.3d 919, 921-22 (8th Cir. 2002). The court may not "weigh the evidence in the summary judgment record, decide credibility questions, or determine the truth of any factual issue." *Kampouris v. St. Louis Symphony Soc.*, 210 F.3d 845, 847 (8th Cir. 2000). The court instead "perform[s] only a gatekeeper function of determining whether there is evidence in the summary judgment record generating a genuine issue of material fact for trial on each essential element of a claim." *Id.*

IV. DISCUSSION

Patent applicants and their representatives have a duty of candor, good faith, and honesty toward the PTO in prosecuting patent applications. *Life Techs v.*

Lonetech Labs., 224 F.3d 1320, 1324 (Fed Cir. 2000). The relevant regulation provides that "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct." 37 C.F.R. § 1.56 (2004). A breach of this duty of good faith is considered inequitable conduct, and this Court may rule patents tainted by that inequitable conduct unenforceable, even though the patents may be valid and even infringed. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1996). Inequitable conduct is an equitable, unclean hands-based doctrine, and will apply in cases "where some unconscionable act of one coming for relief has an immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933); *See Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 807-09 (Fed. Cir. 1990). Inequitable conduct typically takes one of three forms: (1) affirmative misrepresentations of a material fact; (2) failure to disclose material information; or (3) submission of false material information. *Baker Int'l v. McGraw, Inc.*, 149 F.3d 1321, 1327 (Fed. Cir. 1998).

A. Infectious Enforceability

Similarly, a court may find a patent "infected" if the claims of that patent directly relate to the inequitable conduct in the prosecution history of another related patent. *See Consolidated Aluminum*, 910 F.2d at 809-10. Inequitable conduct during prosecution of one patent

can render patents in the same family unenforceable only where the immediate and necessary relationship test is satisfied. *See Consol. Aluminum*, 910 F.2d at 807-09; *Truth Hardware Corp. v. Ashland Prod., Inc.*, 2003 WL 22005839 at *1 (D. Del. 2003); *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elec. Co., Ltd.*, 24 F. Supp.2d 537, 543-44 (E.D. Va. 1998), *aff'd on other grounds*, 204 F.3d 1368, 1378 (Fed. Cir. 2000).

> Pertinent Federal Circuit authority also teaches that the mere occurrence of inequitable conduct in connection with an application within a chain of applications is not enough to invalidate a patent issued as a result of a later application in the chain; instead, the earlier inequitable conduct in the chain must be related to the targeted claims of the ultimately-issued patent or patents sought to be enforced.

Semiconductor Energy, 24 F. Supp.2d at 543.

In each case cited by Monsanto where a court has found a patent to be unenforceable based on infectious unenforceability, the patent application either directly referenced the unenforceable patent in its prosecution history, or the patent in question was a "continuation" of the unenforceable patent. *See Consol. Aluminum*, 910 F.2d at 807-09; *Truth Hardware*, 2003 WL 22005839 at *1; *Semiconductor Energy Lab.*, 24 F. Supp.2d at 543-44. Where a "divisional application" is "for a distinct or independent invention," a "continuation application" is

"for the same invention claimed in a prior application and which is filed before the original application has been abandoned in order to establish the right to further examination of the application. Jane E. Lehman, Anne E. Melley & Elizabeth A. Brainard, *Types of Continuing Applications*, 60 Am. Jur.2d Patents § 325 (2004).

In *Consolidated Aluminum Corporation v. Foseco International Limited*, the court found that the plaintiff had intentionally failed to disclose the best mode and instead disclosed a fictitious, inoperable mode. 910 F.2d 804, 807 (Fed. Cir. 1990). The court held that this behavior constituted inequitable conduct and rendered patent '917 unenforceable. *Id.* at 809. The court went further to declare three other patents unenforceable because of the "taint" of the inequitable conduct relating to patent '917. *Id.* at 809. Patent '081 was unenforceable because it both directly referenced the patent '917 invention and also had the prior undisclosed best mode incorporated in it. *Id.* The other two patents held unenforceable due to the inequitable conduct in the prosecution of patent '917, patents '212 and '303, were continuations of '081. *Id.* Because of how closely related the patents were, the court held that there was an immediate and necessary relationship between the unenforceable '917 patent and the other three patents. *Id.* at 810-12.

In *Semiconductor Energy Laboratory v. Samsung Electronics Company*, the plaintiff disclosed the Japanese translation of Japanese patent '968 with only a short summary in English as prior art during the

prosecution of its U.S. patent '636 application. 24 F. Supp.2d 537, 540-41 (E.D. Va 1998). The court held that the plaintiff concealed material portions of prior art references in patent '968 by misleading the PTO to believe that all the relevant elements were disclosed in the short English summary. *Id.* at 541. Based on this inequitable conduct, the court found that patent '636 was unenforceable. *Id.* at 542. As another independent additional ground of refusing to enforce the '636 patent, the defendant argued that the "taint" of patents '494, '455 and '132 infected patent '636. *Id.* at 545. The District Court recognized that this would be an extension of the current law; however, the issue was not resolved because the court had already found the patent unenforceable.[1] *Semiconductor Energy Lab. Co., Ltd. v. Samsung Electronics Co., Ltd.*, 4 F. Supp.2d 477, 486-87 (E.D. Va. 1998). On a motion for reconsideration, the District Court held that the Plaintiff had not shown any clear error of law in the District Court's opinion; however, the inequitable conduct in the '636 patent chain provided an alternate independent ground for finding the '636 patent unenforceable because of how similar the claims and prosecution history of the related patents

---

1. The Court recognized that none of the prior district court cases specifically involved misrepresentations or nondisclosure "made with respect to an earlier patent in the chain. Instead, the cited cases generally involve misconduct with respect to an earlier patent that is repeated and hence permeates, in a sense, the prosecution of a later, related patent." *Semiconductor Energy Lab.*, 4 F. Supp.2d at n.14.

Furthermore, there are no Federal Circuit cases on point; the issue has only been discussed as dicta. *See Id.* at 486.

were to the claims and history in the '636 patent.[2] *Semiconductor Lab.*, 24 F. Supp.2d at 543-44.

In *Truth Hardware Corporation v. Ashland Products*, the Court specifically noted that the patent it found to be unenforceable was a continuation application of the original patent application; the inequitable conduct was during the prosecution of a patent for the same invention. 2003 WL 22005839 (D. Del. 2003) at *n.1. The Court found that because it was a continuation application, the claims were necessarily related to the claims of the prior application. *Id.* at *2. Because of the inequitable conduct during the prosecution of the prior application, the continuation application was tainted and also unenforceable. *Id.*

In *Baxter International v. McGaw*, the Federal Circuit set forth the rule regarding when infectious unenforceability should not be used to declare a related patent unenforceable. 149 F.3d 1321, 1332 (Fed. Cir. 1998). In this case, the District Court held that the inequitable conduct in the prosecution of the '414 patent rendered patent '554 unenforceable indicating that "all descendants of that application, regardless of whether

---

2. The Court opined that a divisional application may be unenforceable when "(i) there is inequitable conduct with respect to the prosecution of an earlier related application in the chain leading to the challenged patent and (ii) the inequitable conduct relates to the asserted claims of that patent." *Id.* at 543-44. However, the analysis is dictum because the Court had already found the '636 patent unenforceable due to inequitable conduct in its own prosecution history. *See Id.*

the reference is material to those claims, are also 'infected' and unenforceable." *See Id.* at 1331. The Federal Circuit reversed, holding that "where the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application." *Id.* at 1332.

This case is much more like *Baxter* than any of the other previously discussed cases that decided a related patent was unenforceable due to infectious unenforceability. First, the '565 is not a continuation application, but is instead a divisional application. Second, there is no convincing evidence submitted by Monsanto that suggests Bayer referenced or relied on the Jansens' declaration during the prosecution of the '565 patent. Finally, the alleged fraud is not connected to patent '565 because Jansens' declaration does not discuss the patentability of chimeric gene claims.

Divisional Application

In this case, the PTO issued a restriction requirement during the prosecution of the '799 patent requiring that the chimeric gene claims be "restricted out" since the claims were a distinct invention from the remaining plant cell claims in the '799 patent. The chimeric gene claims were cancelled in order to avoid combining two inventions in one patent; there is no

evidence that the cancellation was an effort to distance the chimeric gene claims from the alleged inequitable conduct committed during the prosecution of the '799 patent. In fact, the chimeric gene claims were "restricted out" *prior to* September 1991 when Jansens submitted his declaration.

Reliance on Jansens' Declaration

Monsanto has not submitted any convincing evidence that the PTO directly or indirectly relied on or made reference to the Jansens' declaration during the prosecution of patent '565. The PTO is required to conduct its business exclusively in writing. 37 CFR § 1.2 (2004). These writings become the prosecution history of the patent. Declarations filed during prior applications do not automatically become part of a divisional application. *Patent Office's Manual of Patent Examining Procedure* § 201.06(a), at 200-9 (Aug. 1993) [hereinafter *MPEP*]. The PTO is required to state in writing what it searched or considered during the prosecution in its "Search Notes". MPEP § 717.05(B), at 700-87. This Court assumes that the PTO followed its own rules because Monsanto has presented no evidence to the contrary. *See Genzyme Corp. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1103 n.3 (Fed. Cir. 2004). Monsanto has presented no evidence that the PTO considered Jansens' declaration or its substance during the prosecution of the '565 patent. In fact, Monsanto specifically admitted that it had no evidence when counsel said "there is no way for us to know. . . if the examiner indeed went back or not" (8/20

Tr. 13) and "[w]e don't know what was in the examiner's mind . . ." during the prosecution of patent '565 (8/20 Tr. 52).

Relationship between Jansens' Declaration and the Chimeric Gene Claims

However, assuming *arguendo* that the subject matter of patents '565 and '799 is similar, the claims are not related to the degree necessary for this Court to find patent '565 unenforceable due to infectious unenforceability. *See Consol. Aluminum*, 910 F.2d at 810 (the two patents had an immediate and necessary relation because they had more than just relatedness of subject matter). Jansens' declaration does not discuss patentability of chimeric gene claims. Indeed, those claims were already "restricted out" of '799 prosecution. The sole alleged source of inequitable conduct regards the opinion that "generally any truncated [Bt] gene could be expressed in generally any plant to provide an insect controlling amount of its encoded Bt polypeptide toxin in the so-transformed plant" and is not related to any opinion regarding patentability of chimeric gene claims. This Court is unwilling to stretch this disfavored doctrine to find a patent unenforceable when only a tenuous relationship exists between the two related patents.

Accordingly,

IT IS HEREBY ORDERED that the Monsanto's Motion for Summary Judgment [see doc. #440] is **DENIED.**

Dated this 10th day of January, 2005.

s/ E. Richard Webber
E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE

APPENDIX H — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING AND PETITION FOR REHEARING EN BANC FILED APRIL 17, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1109

MONSANTO COMPANY,

Plaintiff-Appellee,

v.

BAYER BIOSCIENCE N.V.,

Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of Missouri in case no. 4:00-CV-01915, Judge E. Richard Webber.

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

Appendix H

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 24, 2008.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly

Dated: 04/17/2008

APPENDIX I — ERRATA OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED JANUARY 25, 2008

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ERRATA

April 4, 2008

Appeal No. 2007-1109

Precedential Opinion, *Monsanto v. Bayer Bioscience*

Decided: January 25, 2008

On page 3, footnote 5: add ", of the Bt2 class of toxins." at the end of the last sentence.

On page 8, line 6: insert ", including the sequence specific claims," after "rejected all claims"

On page 8, line 24: insert "canceled its broadest claims and" after "In reply to the office action, Bayer"

On page 9, line 25: insert "3.4 kB" after "truncated a"

On page 9, line 25: insert new footnote 9 after "Bt toxin gene": "kB, or kilobases, is a unit of length equal to 1000 base pairs of DNA. The Bt2 toxin gene Bayer was using was also approximately 3.4 kB."

Appendix I

On page 14, footnote 11: replace "at the time, Bayer was arguing that" with "despite having canceled the broader claims `solely to expedite the prosecution of th[e] application, and not to acquiesce to the rejection,' at the time Bayer distinguished Barnes, it was continuing to argue that"

On page 16, line 11: replace "and thus one that encoded" with "which for the Bt2 gene would encode"

On page 16, line 11: insert "smaller than 67 kD and" after "a size" On page 16, footnote 14: delete footnote